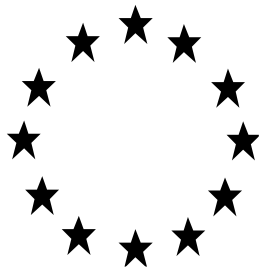
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS



CORPOL TRATAMIENTO DE MADERA ANTIXILOFAGOS

Product type 08

Permethrin as included in the Union list of approved active substances

Case Number in R4BP: BC-VX023597-93

Evaluating Competent Authority: Spain

Date: October 2021

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1 CONCLUSION

Physical-chemical properties and Analytical Methods

CORPOL TRATAMIENTO DE MADERA ANTIXOLÓFAGOS is a transparent light yellow liquid. The density of the product is 765 kg/m^3. The rest of the physical properties such as surface tension and viscosity are within specifications.

The results of the accelerated and long term stability studies showed that the product is stable when stored at 54 ± 2°C for 14 days and at 20°C ± 2°C, for 24 months.
Furthermore, it is not considered to be explosive oxidising or corrosive. The product is classified as flammable liquid cat. 3.
Regarding analytical HPLC-UV can be considered to be acceptable for the identification and quantification of the active substance in the biocidal product "CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS.

Efficacy

The efficacy studies submitted have demonstrated that the product is effective as wood preservative against wood boring insects and termites in Use Class 1 (preventive treatment). The product is intended for professional and non-professional users, which may use it by different application methods (i.e. superficial treatment, e.g. automated spraying, directed spraying and brushing, and treatment by injection).

Sufficient efficacy has been probed for preventive treatment against wood boring insects and termites (*Hylotrupes bajulus, Reticulitermes spp.*) at the applicaction dose of 250 ml/m^2 . In addition sufficient efficacy has been probed for curative treatment against wood boring insects and termites (*Hylotrupes bajulus, Annobium punctatum, Lyctus brunneus* and *Reticulitermes spp.*) at the applicaction dose of 300 ml/m^2.

Human Health

For the classification and labelling of the biocidal product the concentration of active substance and co-formulants in the product is taken into account. In addition to the active substance, other substance of concern for human health have been identified with regard to toxicological properties according to CLP (Regulation (EC) No 1272/2008).
According to the CAR and BPC Opinion for permethrin, is not considered to have endocrine disrupting properties.
After reviewing the potential ED properties of co-formulants, one substance have been identified as having potential endocrine disrupting properties. If these substances are identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised.

After evaluating the exposure and characterizing the risk to human health of the product CORPOL TRATAMIENTO DE MADERA ANTIXILOFAGOS according to the pattern of use requested by the applicant, a maximum dose injection application of 1000ml/m^2 is recommended and the conclusions for each scanario are:

Summary table risk assessment for human health			
Scenario	**Scenario**	**Conclusion**	**Exposed group**
1.	Vacuum-pressure application	A **safe** situation has been for Industrials (Trained professionals) vacuum pressure application when gloves and impermeable coverall (PF 90%) are worn.	Industrial (Trained-Professionals)
2.	Spraying application	An **unsafe** situation has been identified for Professionals and Trained Professionals spraying application.	Trained-Professionals Professionals
3.	Brushing application	A **safe** situation has been identified for Professionals and Trained Professionals brushing when gloves and impermeable coverall (PF 90%) are worn.	Trained-Professionals Professionals
4.	Injection application	A **safe** situation has been identified for Professionals and Trained professionals injection application.	Trained-Professionals Professionals
5.	Handling treated timber	A **safe** situation has been identified for Professionals and Trained professionals handling treated timber when gloves are worn.	Trained-Professionals Professionals
6.	Brushing application	A **safe** situation has been identified for non-professionals brushing.	Non-Professionals
7.	Handling treated timber	A **safe** situation has been identified for non-professionals handling treated timber.	Non-Professionals
8.	Mixing and loading	A **safe** situation has been identified for Trained profesionals, professionals and non-professionals mixing and loading product when gloves and clothes are worn.	Trained-professionals Professionals Non-Professionals
9	Cleaning brush equipment	A **safe** situation has been identified for trained professionals, professionals and non-professionals cleaning brush equipment.	Trained-professionals Professionals Non-Professionals
10.	Cutting and sanding	A **safe** situation has been identified for trained-professionals and professionals cutting and sanding treated wood.	Trained Professionals, Professionals.
11.	Cutting and sanding	A **safe** situation has been identified for trained-professionals and non-professionals for cutting and sanding treated wood.	Non-professionals
12.	Chewing wood off cut	A **safe** situation has been identified for toddler chewing treated wood chips.	General public (toddler-acute)
13.	Playing and mouthing on weathered structure	A **safe** situation has been identified for toddler playing and mouthing on playground weathered wood structure outdoors.	General public (toddler-chronic)
14.	Inhalation residues indoors	A **safe** situation has been identified for general public inhaling volatilised residues indoors.	General public
15.	Laundering contaminated work clothing	A **safe** situation has been identified for trained-professionals and professionals laundering contaminated work clothing at home.	Trained-Professionals, Professionals.

Summary table risk assessment for human health			
Scenario	**Scenario**	**Conclusion**	**Exposed group**
16.	Laundering contaminated work clothing	A **safe** situation has been identified for trained-professionals, professionals and non-professionals laundering contaminated work clothing at home.	Non-professionals.
Combined scenarios 3+8+9+ 15	Brushing + M&L + handling + laundering	A **safe** situation has been identified for Trained-professionals and professionals mixing and loading, brushing, handling wood and cleaning brushes when gloves and impermeable coverall (PF 90%) are worn and laundering clothes without PPEs.	Trained-Professionals, Professionals
Combined scenarios 3+4+8+9 +15	Brushing + Injection + M&L + handling + laundering	A **safe** situation has been identified for non-professionals mixing and loading, brushing and injection application, handling wood and cleqning brushes when gloves and impermeable coverall (PF 90%) are worn and laundering clothes without PPEs.	Trained-Professionals, Professionals
Combined scenarios 6+8+9+ 16	Brushing + M&L + handling + laundering	A **safe** situation has been identified for non-professionals brushing, mixing and loading, handling wood, cleaning brushes and laundering clothes.	Non-Professionals

Environmental Risk

The risk characterizationfor the environemt shows that the intended uses of the biocidal product CORPOL TRATAMEINTO DE MADERA ANTIXILOFAGOS and the use of treated wood in UC 1 and UC 2 do not pose unacceptable risk to the environment if the product is used according to the indications given in the SPC of this product.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier[1]	**Country (if relevant)**
CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS	SPAIN
Additional names: • CORPOL MATACARCOMA • QM TRATAMIENTO MADERA • TM ANTIXILÓFAGOS	SPAIN

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	QUÍMICA DE MUNGUÍA S.A.
	Address	Derio Bidea, 51, 48100 Munguia (Vizcaya) SPAIN
Authorisation number	ES/APP(NA)-2021-08-00778	
Date of the authorisation	07/10/2021	
Expiry date of the authorisation	30/04/2026	

2.1.1.3 Manufacturer(s) of the product

Name of manufacturer	QUÍMICA DE MUNGUÍA S.A.
Address of manufacturer	Derio Bidea, 51, 48100 Munguia (Vizcaya) SPAIN
Location of manufacturing sites	Derio Bidea, 51, 48100 Munguia (Vizcaya) SPAIN

2.1.1.4 Manufacturer(s) of the active substance(s)

Active substance	PERMETHRIN
Name of manufacturer	LANXESS Deutschland GmbH, Germany
Address of manufacturer	Kennedyplatz 1 D-50569 Köln Germany
Location of manufacturing sites	Bayer Vapi Private Limited, Plot # 306/3 II Phase, GIDC Vapi – 396 195 Gujarat India

1 Please fill in here the identifying product name from R4BP.

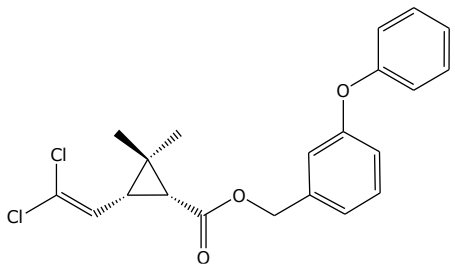
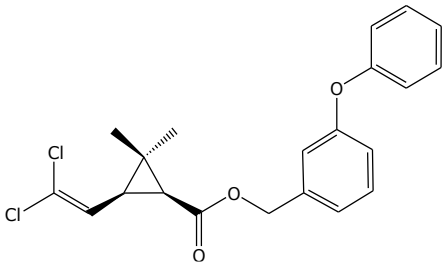
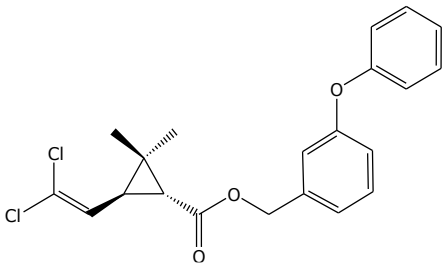
2.1.2 Product composition and formulation

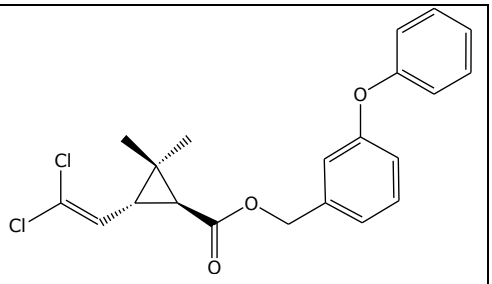
NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☐

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Permethrin
IUPAC or EC name	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
EC number	258-067-9
CAS number	52645-53-1
Index number in Annex VI of CLP	613-058-00-2
Minimum purity / content	>93 %
Structural formula	1Rcis isomer  1Scis isomer  1Rtrans isomer  1Strans isomer

2.1.2.2 Candidate(s) for substitution

There is no indication that Permethrin would fulfil the exclusion criteria specified in article 5(1), nor the substitution criteria specified in Article 10 (1) of Regulation (EU) No 528/2012.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
PREVENTOL HS 75 (Permethrin: ≥90 ≤100 % w/w)	3-phenoxybenzyl (1RS,3RS;1RS,3 SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	52645-53-1	258-067-9	0.35 (technical)
Petrosol D 15/20	Hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, <2% aromatics	Non-active substance	64742-48-9	919-857-5 (Provisional)	92.07
For further details on product composition please refer to the Confidential Annex.					

2.1.2.4 Information on technical equivalence

The source is the approved source from the BPD/BPR process for the active substance Permethrin. Therefore, this source is not a technical equivalence.

2.1.2.5 Information on the substance(s) of concern

According to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017), CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS contains one substance of concern. Please see the confidential annex for further details.

2.1.2.6 Type of formulation

AL: Any other liquid

2.1.3 Hazard and precautionary statements

Classification and labelling of the product according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Flammable liquid 3 Asp. Tox., 1 STOT SE 3 Aquatic Acute 1 Aquatic Chronic 1
Hazard statement	**H226** Flammable liquid and vapour **H304** May be fatal if swallowed and enters airways **H336** May cause drowsiness or dizziness **H400** Very toxic to aquatic life **H410** Very toxic to aquatic life with long lasting effects
Labelling	
Pictograms	 GHS02 GHS08 GHS09 GHS07
Signal words	Danger
Hazard statements	**H226** Flammable liquid and vapour **H304** May be fatal if swallowed and enters airways **H336** May cause drowsiness or dizziness **H410** Very toxic to aquatic life with long lasting effects. **EUH208** Contains Permethrin. May produce an allergic reaction. **EUH066** Repeated exposure may cause skin dryness or cracking
Precautionary statements	<u>For trained professional users</u>: **P210** Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **P261** Avoid breathing vapours. **P271** Use only outdoors or in a well-ventilated area. **P273** Avoid release to the environment. **P280** Wear protective gloves. **P312** Call a POISON CENTER or doctor if you feel unwell **P331** Do NOT induce vomiting **P391** Collect spillage. **P405** Store locked up. **P301+P310** IF SWALLOWED: Immediately call a POISON CENTER/ doctor/... **P303+P361+P353** IF ON SKIN (or hair): Remove/Take off

	immediately all contaminated clothing. Rinse skin with water or shower. **P304+P340** IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing **P370+P378** In case of fire: Use … for extintion **P403+P233+P235** Store in a well-ventilated place. Keep cool. Keep container tightly closed. **P501** Dispose of contents/container as hazardous waste to a registered establishment or undertaking, in accordance with current regulations. <u>For professional users (non-trained professional) and non professional users(general public)</u>: **P101** If medical advice is needed, have product container or label at hand. **P102** Keep out of reach of children. **P210** Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **P261** Avoid breathing vapours. **P271** Use only outdoors or in a well-ventilated area. **P273** Avoid release to the environment. **P280** Wear protective gloves. **P312** Call a POISON CENTER or doctor if you feel unwell **P331** Do NOT induce vomiting **P391** Collect spillage. **P405** Store locked up. **P301+P310** IF SWALLOWED: Immediately call a POISON CENTER/ doctor/... **P303+P361+P353** IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water or shower. **P304+P340** IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing **P370+P378** In case of fire: Use … for extintion **P403+P233+P235** Store in a well-ventilated place. Keep cool. Keep container tightly closed. **P501** Remove the content and /or its container a hazardous waste according to the regulations in force.
Note	

2.1.4 Authorised use(s)

2.1.4.1 Use description 1

Table 1. Use # 1 – Wood preservative - Preventive treatment – Industrial (Trained professional) users

Product Type	PT 8 – Wood preservative
Where relevant, an exact description of the authorised use	Preventive treatment of solid wood (softwood) for Use Class 1 (UC 1) against wood boring insects and termites
Target organism	Wood boring beetles (*Hylotrupes bajulus*) - Larvae

(including development stage)	Subterranean termites (*Reticulitermes spp.*) - Workers, soldiers and nymphs
Field of use	Indoor use (UC 1: situation in which the wood or wood-based product is inside a construction, not exposed to the weather and wetting)
Application method(s)	Superficial application: -Vacuum pressure automated spraying
Application rate(s) and frequency	Ready-to-use product, no dilution required 250 ml/m^2 (product retention 200 g/m^2)
Category(ies) of users	Industrial (Trained professional) users
Pack sizes and packaging material	Can (tin) with 250, 500, 750, 1000, 5000, 10000, 20000 and 25000 ml.

2.1.4.1.1 Use-specific instructions for use

Always read the label or leaflet before use and follow all the instructions provided.

CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS provides preventive treatment of solid wood against insects (when wood is unattacked).

2.1.4.1.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves and impermeable coverall (PF 90%) for mixing and loading and vacuum pressure application (gloves and coverall material to be specified by the authorisation holder within the product information).

Industrial application processes must be carried out within a contained area, situated on impermeable hard standing with bunding to prevent run off and recovery system in place (e.g. sump).

Freshly treated timber must be stored after treatment under shelter or on impermeable hard standing or both,to prevent direct losses to soil,sewer or water and that any losses of the product shall be collected for reuse or disposal.

2.1.4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Please refer to section 2.1.5.1.

2.1.4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

Empty containers, unused product, washing water,containers and other waste generated during the treatment are considered hazardous waste. Deliver those wastes to a registered establishment or undertaking, in accordance with current regulations.

Code the waste according to Decision 2014/955/EU. Do not release to soil,ground,surface water or any kind of sewer.

2.1.4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Please refer to section 2.1.5.1.

2.1.4.2 Use description 2

Table 2. Use # 2 – Wood preservative - Preventive treatment – Trained professionals and Professionals

Product Type	PT 8 – Wood preservative
Where relevant, an exact description of the authorised use	Preventive treatment of solid wood (softwood) for Use Class 1 (UC 1) against wood boring insects and termites.
Target organism (including development stage)	Wood boring beetles (*Hylotrupes bajulus*) - Larvae Subterranean termites (*Reticulitermes spp.*) - Workers, soldiers and nymphs.
Field of use	Indoor use (UC 1: situation in which the wood or wood-based product is inside a construction, not exposed to the weather and wetting).
Application method(s)	Superficial application: -Brushing
Application rate(s) and frequency	Ready-to-use product, no dilution required. 250 ml/m^2 (product retention 200 g/m^2)
Category(ies) of users	Trained professional and professionals users.
Pack sizes and packaging material	Trained-professionals: Can (tin) with 250, 500, 750, 1000, 5000, 10000, 20000 and 25000 ml. Professionals: Can (tin) with 250, 500, 750, 1000 ml.

2.1.4.2.1 Use-specific instructions for use

Always read the label or leaflet before use and follow all the instructions provided. CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS provides preventive treatment of solid wood against insects (when wood is unattacked). During product application (to timbers) and whilst surfaces are drying,do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin)and disposed of in a safe way.

2.1.4.2.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves and coverall for mixing and loading and

protective chemical resistant gloves and coverall (PF 90%) for application (gloves and coverall material to be specified by the authorisation holder within the product information).

2.1.4.2.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Please refer to section 2.1.5.1.

2.1.4.2.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

Trained professional

Empty containers, unused product,washing water,containers and other waste generated during the treatment are considered hazardous waste. Deliver those wasted to a registered establishment or undertaking,in accordance with current regulations.

Code the waste according to Decision 2014 /955 / EU.

Do not release to soil, ground, surface water or any kind of sewer.

Professional

Empty containers, unused product and other waste generated during the treatment are considered hazardous waste. Dispose of in accordance with current regulations.

Do not release to soil, ground surface water or any kind of sewer.

2.1.4.2.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Please refer to section 2.1.5.1.

2.1.4.3 Use description 3

Table 3. Use # 3 – Wood preservative - Curative treatment – Trained professionals and Professionals

Product Type	PT 8 – Wood preservative
Where relevant, an exact description of the authorised use	Curative treatment of solid wood (softwood and hardwood) against wood boring insects and termites
Target organism (including development stage)	Wood boring beetles, House longhorn beetle (*Hylotrupes bajulus*) – Larvae; Common furniture beetle (*Anobium punctatum*) – Larvae; Powder post beetles (*Lyctus brunneus*) - Larvae

	Subterranean termites (*Reticulitermes spp*.)
Field of use	Indoor use
Application method(s)	Superficial application: -Brushing For intensive treatment: Injection application with a syringe or with a brush to existing and controllable number of holes. To be applied in combination with superficial treatment.
Application rate(s) and frequency	Ready-to-use product, no dilution required Superficial: 300 ml/m^2 (product retention 240 g/m^2) Injection: 1000 ml/m^2
Category(ies) of users	Trained professional and professional users
Pack sizes and packaging material	Trained professionals: Can (tin) with 250, 500, 750, 1000, 5000, 10000, 20000 and 25000 ml. Professionals: Can (tin) with 250, 500, 750, 1000 ml.

2.1.4.3.1 Use-specific instructions for use

Always read the label or leaflet before use and follow all the instructions provided.

CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS provides curative treatment of solid wood against insects (when wood is attacked).

During product application (to timbers) and whilst surfaces are drying do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin) and disposed of in a safe way.

2.1.4.3.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves and coverall for mixing and loading and protective chemical resistant gloves (PF 90%) for application (gloves and coverall material to be specified by the authorisation holder within the product information).

2.1.4.3.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Please refer to section 2.1.5.1.

2.1.4.3.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

<u>Trained professional</u>

Empty containers, unused product, washing water, containers and other waste generated during the treatment are considered hazardous waste. Deliver those wastes to a registered establishment or undertaking, in accordance with current regulations.

Code the waste according to Decision 2014 /955 / EU. Do not release to soil, ground, surface water or any kind of sewer <u>Professional</u> Empty containers, unsused product and other waste generated during the treatment are considered hazardous waste. Dispose of in accordance with current regulations. Do not release to soil, ground, surface water or any kind of sewer.

2.1.4.3.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Please refer to section 2.1.5.1.

2.1.4.4 Use description 4

Table 4. Use # 4 – Wood preservative - Preventive treatment – Non-professionals

Product Type	PT 8 – Wood preservative
Where relevant, an exact description of the authorised use	Preventive treatment of solid wood (softwood) for Use Class 1 (UC 1) against wood boring insects and termites
Target organism (including development stage)	Wood boring beetles (*Hylotrupes bajulus*) - Larvae Subterranean termites (*Reticulitermes spp.*) - Workers, soldiers and nymphs
Field of use	Indoor use (UC 1: situation in which the wood or wood-based product is inside a construction, not exposed to the weather and wetting)
Application method(s)	Superficial application: Brushing or rolling
Application rate(s) and frequency	Ready-to-use product, no dilution required 250 ml/m^2 (product retention 200 g/m^2)
Category(ies) of users	Non-professional users (General public)
Pack sizes and packaging material	Can (tin) with 250, 500, 750, 1000 ml

2.1.4.4.1 Use-specific instructions for use

Always read the label or leaflet before use and follow all the instructions provided. CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS provides preventive treatment of solid wood against insects (when wood is unattacked). Before treatment, cover floor around and under object to treat with a disposable, non-permeable protection sheet (e.g.plastic) to avoid spilling of product on the floor.

Please refer to section 2.1.5.1.

2.1.4.4.2 Use-specific risk mitigation measures

Please refer to section 2.1.5.1.

2.1.4.4.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Please refer to section 2.1.5.1.

2.1.4.4.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

Non-professionals: Empty containers,unused product and other waste generated during the treatment are considered hazardous waste. Dispose of in accordance with current regulations. Do not release to soil,ground,surface water or any kind of sewer. Please refer to section 2.1.5.1.

2.1.4.4.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Please refer to section 2.1.5.1.

2.1.4.5 Use description 5

Table 5. Use # 5 – Wood preservative - Curative treatment – Non-professionals

Product Type	PT 8 – Wood preservative
Where relevant, an exact description of the authorised use	Curative treatment of solid wood (softwood and hardwood) against wood boring insects and termites
Target organism (including development stage)	Wood boring beetles, House longhorn beetle (*Hylotrupes bajulus*) – Larvae; Common furniture beetle (*Anobium punctatum*) – Larvae; Powder post beetles (*Lyctus brunneus*) - Larvae Subterranean termites (*Reticulitermes spp*.)
Field of use	Indoor use
Application method(s)	Superficial application: Brushing or rolling For intensive treatment: Injection application with a brush to existing and controllable number of holes. To be applied in combination with superficial treatment.
Application rate(s) and	Ready-to-use product, no dilution required

frequency	Superficial: 300 ml/m^2 (product retention 240 g/m^2) Injection: 1000 ml/m^2
Category(ies) of users	Non-professional users
Pack sizes and packaging material	Can (tin) with 250, 500, 750, 1000 ml.

2.1.4.5.1 Use-specific instructions for use

Always read the label or leaflet before use and follow all the instructions provided.

CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS provides curative treatment of solid wood against insects (when wood is attacked).

Before treatment, cover floor around and under object to trat with a disposable , non-permeable protection sheet (e.g. plastic) to avoid spilling of product on the floor.

2.1.4.5.2 Use-specific risk mitigation measures

Please refer to section 2.1.5.1.

2.1.4.5.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Please refer to section 2.1.5.1.

2.1.4.5.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

Empty containers,unused product and other waste generated during the treatment are considered hazardous waste. Dispose of in accordance with current regulations.

Do not release to soil,ground,surface water ar any kind of sewer.

2.1.4.5.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Please refer to section 2.1.5.1.

2.1.5 General directions for use

2.1.5.1 Instructions for use

Before using the product carefully read the precautions.

The premises where the application is made must be ventilated adequately during and after the treatment.

The product is intended to be applied directly on diferent types of wood such as parquet, flooring, wood decor (plinths, friezes, baseboards), carpentry (doors and windows), structural timber (beams, cabrio, solivas, etc.), furniture and works of art.

After the product application, 12 hours must be respected before taking contact with the treated wood. If it is necessary, another treatment on the wood can be applied and additional 12 hours should be respected as well (24 hours in total).

Before applying over the entire surface of the wood, it is advisable to test on a non visible part to ensure that it does not affect the finished of the product.

It should not be mixed with any other chemical.

The users should inform if the treatment is ineffective and report straightforward to the registration holder.

The product can be harmful to protected species such as bats, hornets or birds. The presence of protected species in the area to be treated must be assessed prior to use of the product. Appropriate protective measueres must be taken if necessary.

2.1.5.2 Risk mitigation measures

Keep children and pets away from treated surfaces until dried.

Keep away from food, drink or animal feedstuffs.

Do not use on wood which may come in direct contact with food, feeding stuff, and livestock animals.

Avoid prolonged contact of pets to treated surfaces.

Contain permethrin (pyrethroids), may be lethal to cats. Cats must be avoid contact with treated object area.

2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

First aid instructions

Poisoning may cause:

Eye and skin irritation. Alteration of nervous system. Chemical pneumonia by aspiration.

First aid:

Remove the person from contaminated area.

Remove contaminated clothing.

In the case of contact with eyes, rinse with plenty of water for at least 15 minutes. Remember to remove the contact lenses.

Wash skin with soap and water, without rubbing.

Never give anything by mouth. Do not induce vomiting.

Check breathing, if necessary, provide artificial respiration.

Take the patient to hospital and take the container or label.

DO NOT LEAVE THE INTOXICATED PERSON ALONE AT ANY TIME.

Therapeutic advice for physicians and health staff:

Symptomatic treatment.

Environmental precautions:
Avoid dispersal of spilt material and runoff and contact with soil,waterways,drains and sewers. Inform to the relevant authorities if the product has caused environmental pollution (sewers,waterways,soil or air).

Methods and materials for containment and cleaning up:
Channelling large quantities and collect in containers;dispose them according to local regulations. Wash the small amounts with water. Remove the used water according to local regulations.

2.1.5.4 Instructions for safe disposal of the product and its packaging

See sections 2.1.4.1.4, 2.1.4.2.4,2.1.4.3.4,2.1.4.4.4 and 2.1.4.5.4.

2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Keep put of sun exposure and frost.
Store in the original container.
Store in a dry place in closed containers.
Sehlf life : 2 years

2.1.6 Other information

According to national legislation, in Spain there are until three user categories:

- Trained professional users (TP): pest control operators, having received specific training in biocidal product uses according to the national legislation in force.
- Professional users (NTP): professionals that use the biocidal products in the context of his profession, that is not pest control operator, and that are unlikely to have received any specific training in biocidal product use according to the national legislation in force. It can be expected that they have some knowledge and skills handling chemicals (if they must use it in their job) and they are able to use correctly some kind of PPE if necessary.
- Non-professional users (NP): users who are not professionals and that apply the biocidal product is in his private life.

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Can/Tin	250 ml	Iron	Easy Open Cap	Industrials, Trained	Yes

				Professionals, Professionals and Non-professionals	
Can/Tin	750 ml	Iron	Easy Open Cap	Industrials, Trained Professionals, Professionals and Non-professionals	Yes
Can/Tin	1000 ml	Iron	Easy Open Cap	Industrials, Trained Professionals, Professionals and Non-professionals	Yes
Can/Tin	5000 ml	Iron	Easy Open Cap	Industrials, Trained Professionals	Yes
Can/Tin	10000 ml	Iron	Easy Open Cap	Industrials, Trained Professionals	Yes
Can/Tin	20000 ml	Iron	Easy Open Cap	Industrials, Trained Professionals	Yes
Can/Tin	25000 ml	Iron	Easy Open Cap	Industrials, Trained Professionals	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Please refer to the reference list included in the corresponding Annex and also in Section 13 of the IUCLID dossier

2.1.8.2 Access to documentation

The applicant provided a letter of access from Lanxess Deutschland GmbH, to the dossier assessed for the approval (respectively the inclusion into Annex I of Directive 98/8/EC18) of the active substance Permethrin for use in wood preservative (product-type 08).

2.2 Assessment of the biocidal product

2.2.1 Intended use(s) as applied for by the applicant

Table 2-4. Intended use # 1 – Industrial use[2]

Product Type(s)	PT 8 – Wood preservative
Where relevant, an exact	The product is intended to be applied by automated spraying

2 Copy this section as many times as necessary (one table per use).

description of the authorised use	in industrial premises to prevent the presence of woodworm and termite species in the wood. The product is intended to be applied indoor (classified as use classes 1 and 2). The product is intended to be applied on different types of wood or furniture such as parquet, flooring, wood decor (plinths, friezes, baseboards) and carpentry (doors and windows) and structural timber (beams, cabrio, solivas, ...). Depending on whether the wood has already been attacked or not, the treatment can be curative or preventive
Target organism (including development stage)	*Reticulitermes sp.*, *Hylotrupes bajulus*, *Annobium punctatum* and *Lyctus brunneus*
Field of use	The product is intended to be classified as use classes 1 and 2
Application method(s)	**Automatic spray**: The spraying process is performed by automated machines in hermetic closed tanks at indoor industrial premises without operator presence during the application. This method may be developed by industrial user for preventive or curative treatments
Application rate(s) and frequency	250 ml/m^2 for preventive treatment 300 ml/m^2 for curative treatment
Category(ies) of user(s)	Industrial user
Pack sizes and packaging material	Iron can of the following sizes: 250 cc 500 cc 750 cc 1000 cc 5000 cc 10000 cc 20000 cc 25000 cc

Table 2-3. Use # 2 – Professional use

Product Type	PT 8 – Wood preservative
Where relevant, an exact description of the authorised use	The product is intended to be applied to prevent the presence of woodworm and termite species in the wood. The product is intended to be applied indoor (classified as use classes 1 and 2). The product is intended to be applied on different types of wood or furniture such as: • Parquet, flooring, wood decor (plinths, friezes, baseboards) and carpentry (doors and windows) and structural timber (beams, cabrio, solivas, ...). Product can be applied by brushing, injection or localized and directed spraying. Depending on whether the wood

	has already been attacked or not, the treatment can be curative or preventive: - Curative treatment (attacked wood) If the attack is low (a controllable number of holes), treat holes directly by injection. If the attack is strong (large number of holes) and the wood is damaged, remove any possible varnish, paint, etc. and applied by brushing, directed spraying or by injection. - Preventive treatment (unattacked wood) If the wood is finished from varnish, paint, wax, etc. remove the varnish, paint, etc. and once the wood is cleaned, apply the product by brushing or spraying. If the wood is new wood (unfinished or untreated): Clean the surface and apply by brushing, automated spray (industrial use only) or directed spray. • Furniture and works of art: Inject into the holes of insects. Brushing all unvarnished or polychrome areas (back of the cabinet, bottom drawer, etc).
Target organism (including development stage)	*Reticulitermes sp.*, *Hylotrupes bajulus*, *Annobium punctatum* and *Lyctus brunneus*
Field of use	The product is intended to be classified as use classes 1 and 2
Application method(s)	Three application methods are defined for professional user: • **Spray application:** Spraying is performed by the operator to the wood surfaces to be treated by a handheld or knapsack sprayer. The necessary quantity of the product must be taken from the package and introduce in the sprayer. The product is sprayed in indoor premises: parquet, flooring, wood decor (plinths, friezes, baseboards) and carpentry (doors and windows) • **Brushing**: The user applies the product over the wood with a brush or roller. Two treatments curative or preventive will be applied. • **Injection:** The application by injection will be only applied as a curative treatment. The product is injected into the wood by means of a bomb or an injector which are placed on the wood or with the help of the brush.
Application rate(s) and frequency	250 ml/m^2 for preventive treatment 300 ml/m^2 for curative treatment.
Category(ies) of users	Professional user
Pack sizes and packaging material	Iron can of the following sizes: 250 cc 500 cc

	750 cc 1000 cc 5000 cc 10000 cc 20000 cc 25000 cc

Table 1-4. Use # 3 – Non Professional use

Product Type	PT 8 – Wood preservative
Where relevant, an exact description of the authorised use	The product is intended to be applied to prevent the presence of woodworm and termite species in the wood. The product is intended to be applied indoor (classified as use classes 1 and 2). • The product is intended to be applied on different types of wood or furniture such as parquet, flooring, wood decor (plinths, friezes, baseboards) and carpentry (doors and windows) and structural timber (beams, cabrio, solivas, ...). Product can be applied by brushing and injection. Depending on whether the wood has already been attacked or not, the treatment can be curative or preventive: - Curative treatment (attacked wood) If the attack is low (a controllable number of holes), treat holes directly by injection. If the attack is strong (large number of holes) and the wood is damaged, remove any possible varnish, paint, etc. and applied by brushing or by injection. - Preventive treatment (unattacked wood) If the wood is finished from varnish, paint, wax, etc. remove the varnish, paint, etc. and once the wood is cleaned, apply the product by brushing. If the wood is new wood (unfinished or untreated): Clean the surface and apply by brushing. • Furniture and works of art: Inject into the holes of insects. Brushing all unvarnished or polychrome areas (back of the cabinet, bottom drawer, etc).
Target organism (including development stage)	*Reticulitermes sp.*, *Hylotrupes bajulus*, *Annobium punctatum* and *Lyctus brunneus*
Field of use	The product is intended to be classified as use classes 1 and 2
Application method(s)	Two application methods are defined for non-professional user:

	• Brushing: The user applies the product over the wood with a brush or roller. Two treatments curative or preventive will be applied. • Injection: The application by injection will be only applied as a curative treatment. The product is injected in the wood with the help of the brush.
Application rate(s) and frequency	250 ml/m^2 for preventive treatment 300 ml/m^2 for curative treatment.
Category(ies) of users	Non-Professional user
Pack sizes and packaging material	Iron can of the following sizes: 250 cc 500 cc 750 cc 1000 cc

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual method	Permethrin 0.368%	Liquid At initial time: Transparent light yellow liquid. After 14 days at 54ºC: Transparent yellow liquid. After 7 days at 0ºC: Transparent light yellow liquid	Report No. 402/15/1187F-e. FCBA
Colour at 20 °C and 101.3 kPa	Visual method		Transparent light yellow	Report No. 402/15/1187F-e. FCBA
Odour at 20 °C and 101.3 kPa			Not specified	
Acidity / alkalinity	-	-	The water solubility of the product does not reach the minimum required for testing of acidity and alkalinity. Therefore, it is not technically possible to be performed.	-
Relative density / bulk density	OECD Guideline 109 (Density of Liquids and Solids)	Permethrin 0.368 %	Density: 765 kg/m^3 at 20.0 ± 2ºC. The relative density D_4^{20} = 0.765.	Report No. 402/15/1187F-e. FCBA
Storage stability	CIPAC MT 46.1	Permethrin 0.368 %	Temperature: 54°C- Time: 14	Report No. 402/15/1187F-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
test **accelerated storage**	(Storage Stability)		<u>days</u> $[C]_0$ = 0.312% $[C]_f$ =0.296 % $\Delta[C]$ = -5.1 % < 10% The results fulfils the Guidence criteria. No significant change of the active substance contents was observed.	e. FCBA
Storage stability test **long term storage at ambient temperature**	FCBA Internal Method	Permethrin 0.368 %	<u>Temperature: 20°C- Time: 2 years</u> <u>12 months</u> $[C]_0$ = 0.368% $[C]_f$ =0.394 % $\Delta[C]$ = 7.06 % < 10% <u>18 months</u> $[C]_0$ = 0.368% $[C]_f$ =0.395 % $\Delta[C]$ = 7.33 % < 10% <u>24 months</u> $[C]_0$ = 0.368% $[C]_f$ =0.391 % $\Delta[C]$ = 6.25 % < 10% The appearance of the commercial packaging and the weight of the test item in the commercial packaging did not change significantly after 24 months at 20°C	Report No. COA-402/15/1187F/1/k/T24M-e. FCBA
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3 (Low temperature stability test (liquids))	Permethrin 0.368 %	No deposit or phase partition was observed. The test item was physically stable after 7 days at 0 ± 2ºC.	Report No. 402/15/1187F-e. FCBA
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	This study is not needed as the product may be kept out of sun exposure during storage.			
Effects on content of the active substance	Please refer to the Storage stability test.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
and technical characteristics of the biocidal product – **temperature and humidity**				
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Please refer to the Storage stability test.			
Wettability	Not applicable for this type of product.			
Suspensibility, spontaneity and dispersion stability	Not applicable for this type of product.			
Wet sieve analysis and dry sieve test	Not applicable for this type of product.			
Emulsifiability, re-emulsifiability and emulsion stability	Not applicable for this type of product.			
Disintegration time	Not applicable for this type of product.			
Particle size distribution, content of dust/fines, attrition, friability	Not applicable for this type of product.			
Persistent foaming	Not applicable for this type of product.			
Flowability/Pourability/Dustability	Not applicable for this type of product.			
Burning rate — smoke generators	Not applicable for this type of product.			
Burning completeness — smoke generators	Not applicable for this type of product.			
Composition of	Not applicable for this type of product.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
smoke — smoke generators				
Spraying pattern — aerosols	Not applicable for this type of product.			
Physical compatibility	The product is not intended to be used in combination with other products or active substances.			
Chemical compatibility	The product is not intended to be used in combination with other products or active substances.			
Degree of dissolution and dilution stability	Not applicable for this type of product.			
Surface tension	EC method A.5, OECD 115 and NF EN 14370	Permethrin 0.368%	22.56 mN/m at 20.0 ± 0.5ºC. The test item was considered as surface active in the experimental conditions used.	Report No. 402/15/1187F-e. FCBA
Viscosity	OECD 114 and NF EN ISO 2431	Permethrin 0.368%	Kinematic viscosity (mm^2/s) < 6.62 at 20ºC Kinematic viscosity (mm^2/s) < 6.62 at 40ºC	Report No. 402/15/1187F-e. FCBA

Conclusion on the physical, chemical and technical properties of the product
CORPOL TRATAMIENTO DE MADERA ANTIXOLÓFAGOS is a transparent light yellow liquid. The density of the product is 765 kg/m^3 at 20.0 ± 2ºC. (relative density value 0.765), the kinematic viscosity < 6.62 mm^2/s at 20ºC and at 40 ºC, and a surface tension of 22.56 mN/m at 20.0 ± 0.5ºC. The results of the accelerated and long-term stability studies showed that the product is stable when stored at 54 ± 2°C for 14 days and at 20°C ± 2°C, for 24 months. Under this conditions, the concentration of the active substance was within the specifications. Regarding the storage stability at low temperature it can be concluded that the product was physically stable after 7 days at 0 ± 2ºC. No deposit or phase partition was observed. There are no changes in the aspect of the solution or signs of deterioration in the package proposed for commercialization. Based on the results obtained, a validity period of 24 months from the date of manufactured is proposed.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive properties.			
Flammable gases	Not applicable. The study does not need to be conducted because the			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	product is a liquid.			
Flammable aerosols	Not applicable. The study does not need to be conducted because the product is a liquid.			
Oxidising gases	The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with oxidising properties and hence, the classification procedure does not need to be applied.			
Gases under pressure	The study does not need to be conducted because the substance is a liquid			
Flammable liquids	Obsolete as covered by section 'Flash point'			
Flash point Test	ISO 2719 and EU Method A.9	Permethrin 0.368%	The flash point of the test item was 39.9ºC under the conditions of the test.	Report No. 402/15/1187F-e. FCBA
Flammable solids	Not applicable. The study does not need to be conducted because the product is a liquid.			
Self-reactive substances and mixtures	The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied.			
Pyrophoric liquids	Not applicable.			
Pyrophoric solids	Not applicable.			
Self-heating substances and mixtures	Not applicable.			
Substances and mixtures which in contact with water emit flammable gases	Not applicable, there are no chemical groups present in the molecule which in contact with water are capable to emit flammable gases.			
Oxidising liquids	There are no chemical groups associated with oxidising properties present in the molecule. Therefore, this study is not necessary.			
Oxidising solids	Not applicable. The study does not need to be conducted because the product is a liquid			
Organic peroxides	The study does not need to be conducted because the substance does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of test and criteria			
Corrosive to metals	UN Test C1	Permethrin 0.35%	The test item Corpol Tratamiento de madera antixilofagos was not considered to be corrosive to steel under the testing conditions.	REPORT No.402121I1114Fa-e.
Auto-ignition temperatures of products (liquids and gases)	EU Method A.5	Permethrin 0.352%	The test item has been determined to have an auto-ignition temperature of 256 ± 5°C	Report No DS76HT. Envigo Research Limited
Relative self-ignition temperature for solids	Not applicable. The study does not need to be conducted because the product is a liquid			
Dust explosion hazard	Not applicable. The study does not need to be conducted because the product is a liquid.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Conclusion on the physical hazards and respective characteristics of the product				
CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS product is not considered to be explosive,as no chemical structures that have explosive propoerties are present in te formulation. The flash point of the test item was 39.9ºC. The auto-ignition temperature was 256 ± 5°C.				

2.2.4 Methods for detection and identification

[Description of analytical methods used for the analysis of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product]

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Permethrin	HPLC-UV	2x6 spiking at 100 mg/L	r > 0.99 or greater	Yes	99.50%-100.00%	99.76	0.3983 %		Report No. 402/15/1187 F-e. FCBA

Conclusion on the methods for detection and identificationof the product
This analytical method for determination of Permethrin (active substance) was successfully validated according to SANC0/3030/99 rev.4.

2.2.5 Efficacy against target organism

2.2.5.1 Function and field of use

CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS is a wood preservative (PT 8) for trained professional, professional and general public users.

CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS contains 0.35% w/w of permethrin and is intended for preventive (UC 1) and curative treatment of solid wood.

The treatment with the biocidal product is performed by superficial application (automated spray, directed spray, brushing) and by injection application in combination with the superficial treatment.

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS is a wood preservative that provides preventive and curative treatment against wood boring insects and termites.

The product is intended to be used to protect solid wood for the following field of use:
Use Class 1: situation in which the wood or wood-based product is inside a construction, not exposed to the weather and wetting.

The objects to be protected are articles and structures made of wood, such as parquet, flooring, wood decor (plinths, friezes, baseboards), furniture, carpentry (doors and windows), structural timber (beams, cabrio, solivas) and works of art.

2.2.5.3 Effects on target organisms, including unacceptable suffering

CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS contains 0.35% w/w of the active substance Permethrin. in treated wood acts as an insecticide against adult and larval wood-boring pests of insects by killing them.

It is not possible to assess unacceptable suffering.

2.2.5.4 Mode of action, including time delay

According to IRAC, Permethrin (CAS N°52645-53-1) is an insecticide in the pyrethroid chemical family, considered type I pyrethroid that acts on the nervous system of insects. It interferes with sodium channels to disrupt the function of neurons, and causes muscles to spasm, culminating in paralysis and death. Permethrin can be effective by contact or ingestion and also acts as a mild repellent.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system /concentrations applied / exposure time**	**Test results: effects**	**Reference**
Wood preservative - Preventive treatment	Use Class 1	CORPOL TRATAMIENTO DE MADERA ANTIXILOFAGOS 0.35% w/w Permethrine	Wood boring beetles: *Hylotrupes bajulus* (recently hatched larvae) 10 larvae/replicate 6 treated replicates and 6 untreated replicates	EN 46-1 EN 73 (ageing by evaporation)	Softwood (*Pinus sylvestris*, sapwood) Application by brushing Concentration of product applied: 200 g/m^2. Exposure time: 28 d	100% mortality of larvae Mean measured retention 199.34 g/m^2 ≈ 249.17 ml/m^2 In untreated control samples, mortality of larvae was <30%. Study is valid.	[redacted] Report No. 401/15/230F/a. (2016)
Wood preservative -	Use Class 1	CORPOL TRATAMIENTO DE	Wood boring beetles:	EN 47:1992 +	Softwood (*Pinus sylvestris*,	100% mortality of larvae at ≥19.06 Kg/m^3 mean	[redacted] Report No. 10583

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system /concentrations applied / exposure time**	**Test results: effects**	**Reference**
Preventive treatment Preventive action (threshold of effectiveness)		MADERA ANTIXILOFAGOS 0.35% w/w Permethrine	*Hylotrupes bajulus* (recently hatched larvae) 5 replicates/treatment 6 larvae/replicate	EN 73:1992 (ageing by evaporation)	sapwood) Impregnation by vacuum/pressure Concentrations of product diluted in xylene, applied in test: 0%, 3.8%, 5.6%, 7.5%, 10.3% y 13.1%. Controls included (0%, no solvent). Exposure time: 12 weeks	retention in the treated wood (i.e. ≥3.8% w/w dilution). Mean solution retentions: 0, 19.06, 27.56, 37.51, 50.42, 64.16 kg/m3. In untreated samples (with and without solvent), mortality of larvae was <30%. Study is valid.	(2005)
Wood preservative - Preventive treatment	Use Class 1	CORPOL TRATAMIENTO DE MADERA ANTIXILOFAGOS 0.35% w/w Permethrine	Termites: *Reticulitermes grassei* 6 treated replicates 3 untreated replicates Workers, soldiers, nymphs.	EN 118:2013 + EN 73:2013 (ageing by evaporation)	Softwood (*Pinus sylvestris*, sapwood) Application by brushing Concentration of product applied: 200 g/m^2. Exposure time: 8 weeks	Mean measured product retention: 198.18 g/m^2. This corresponds to application rate of 247.75 ml/m^2. Treated samples showed attack level of 1 in 5 samples and 0 in 1 sample. 100% mortality of termites. Controls showed attack level of 4 in the 3 samples. >50% survival of termites in controls. Study is valid.	[redacted] Report No. 062358-1-a. (2017)
Wood preservative - Preventive treatment (threshold of	Use Class 1	CORPOL MATACARCOMA DEODORIZED	Termites: *Reticulitermes spp.* 3 replicates/treatment	EN 117:1989 + EN 73:1988 (ageing by evaporation)	Softwood (*Pinus sylvestris*, sapwood) Impregnation by vacuum/pressure process	Product prevents action of termites at ≥3% dilution, corresponding to mean retention of ≥14.4 Kg/m^3. Attack level was 1, 1, 0 in the three wood samples.	[redacted] Report No. 9855.3 (2004)

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system /concentrations applied / exposure time**	**Test results: effects**	**Reference**
effectiveness)			Workers, soldiers, nymphs.		Concentrations of product diluted in xylene, applied in test: 0, 3, 4.5, 5.75, 8 and 11%. Exposure time: 8 weeks	This corresponds to a mean retention of ≥28.8 g/m^2 and an application rate of 36 ml/m^2. Mean measured solution retentions: 0, 14.4, 19.6, 24.5, 31.7, 42.5 kg/m^3. Controls showed attack level of 4 in the 3 wood samples. Survival of termites in controls was not reported, apparently by mistake . Validity of study cannot be fully checked. However in solvent controls survival of >50% termites was reached.	
Wood preservative - Curative action	Use Class 1	CORPOL TRATAMIENTO DE MADERA ANTIXILOFAGOS 0.35% w/w Permethrine	Wood boring beetles: *Hylotrupes bajulus* (larvae) 10 treated replicates 2 untreated replicates 6 larvae/replicate	EN 1390:2006	Softwood (*Pinus sylvestris*, sapwood) Application by brushing Concentrations applied: 300 ml/m^2 Exposure time: 24 weeks	93.2% mean mortality of larvae in treated samples (i.e. >80% mortality) Mean measured dose was 299.85 ml/m^2 (≈ 240 g/m^2) Untreated controls: 0% mortality of larvae. Study is valid since at least 9 larvae of the 12 initially introduced were alive at the end of test.	[redacted] Report No. 401/15/230F/c. (2016)
Wood preservative - Curative action	Use Class 1	CORPOL TRATAMIENTO DE MADERA ANTIXILOFAGOS 0.35%	Wood boring beetles: *Hylotrupes bajulus* (larvae) 30 larvae of 50-	EN 22:1982	Softwood (*Pinus sylvestris*, sapwood) Application by brushing	81.2% mean mortality of larvae in treated samples (i.e. >80% mortality). Mean measured dose was 222.2	[redacted] Report No. 10583 (2005)

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system /concentrations applied / exposure time**	**Test results: effects**	**Reference**
		w/w Permethrine	100 mg 30 larvae of 101-150 mg 4 treated replicates, 1 untreated replicate		Concentrations applied: 200-250 g/m^2. Exposure time: 12 weeks	g/m^2 (≈ 277.75 ml/m^2). Untreated control: 8.3% mortality of larvae. Study is valid since larvae survival was >80% at test end.	
Wood preservative - Curative action	Use Class 1	CORPOL TRATAMIENTO DE MADERA ANTIXILOFAGOS 0.35% w/w Permethrine	Wood boring beetles: *Lyctus brunneus* (larvae) 5 treated replicates 3 untreated replicates Larvae per replicate not reported	Pr NF X41-665[3]	Hardwood (*Quercus robur*) Application by brushing Concentrations applied: 200 g/m^2. Exposure time: 12 weeks	0% emergence of adults occurred and 0% alive larvae in the treated samples. Mean measured retention was 201.2 g/m^2 (≈ 251.5 ml/m^2). In untreated samples 86.3% of insects (mean) were alive at test end (i.e. >80%). Study is valid.	[redacted] Report No. 401/15/230F/e-e. (2017)
Wood preservative - Curative action	Use Class 1	CORPOL TRATAMIENTO DE MADERA ANTIXILOFAGOS 0.35% w/w Permethrine	Wood boring beetles: *Anobium punctatum* 12 larvae of 2-5 mg per replicate 6 treated replicates 3 untreated replicates	EN 48	Softwood (*Pinus sylvestris*, sapwood) Application by brushing Concentrations applied: 300 ml/m^2. Exposure time: 8 weeks	100% dead larvae in the treated samples (i.e. >80% mortality). Mean measured dose was 295.17 ml/m^2 (≈ 236.13 g/m^2). In untreated samples 92% of larvae (mean) were alive at test end (i.e. >70%). Study is valid.	[redacted] Report No. 401/15/230F/d-e (2018)

[3] Pr NF X41-665 (2015) Determination of curative efficacy against Lyctus brunneus (Stephens) (laboratory method)

Conclusion on the efficacy of the product

The Applicant has submited the following studies against wood boring insects and termites to demonstrate the efficacy of CORPOL TRATAMIENTO DE MADERA ANTIXILOFAGOS, which are required according to the EN 599-1 for preventive use and the EN 14128 for curative use to prove efficacy for Use Class 1 wood as defined in the EN 335.

- In order to demonstrate preventive treatment against larvae of *Hylotrupes bajulus* in softwood, a valid study following EN 46-1 + EN 73 was presented. 100% mortality of larvae was found at the measured retention of 199 g/m^2. Considering the density of the product, this corresponds to an application rate of 249 ml/m^2. Thus the dose of 250 ml/m^2 recommended by the Applicant for preventive treatment is acceptable.

- In addition to demonstrate preventive treatment against larvae of *Hylotrupes bajulus* in softwood, a valid study following EN 47 + EN 73 was presented. 100% mortality of larvae was found at mean retention of ≥19.06 Kg/m^3 in the treated wood which was achieved by immersion of wood samples in a product dilution of ≥3.8% w/w. The efficacious retention of ≥19.06 Kg/m^3 would correspond to an application rate of ≥38.1 g/m^2, and considering the density of the product, this would correspond to an application rate of 47.65 ml/m^2. Thus the recommended dose of 250 ml/m^2 for preventive treatment is acceptable.

The former studies with *Hylotrupes bajulus* are sufficient to probe the preventive efficacy of the product. The general label claim 'against wood boring beetles' with a mention 'against house longhorn beetle' can be authorised. However mentions to other other species cannot be accepted.

- In order to demonstrate curative treatment against larvae of *Hylotrupes bajulus* in softwood, a valid study following EN 1390 was presented. 93.2% mortality of larvae was found at the measured dose of 299.85 ml/m^2. Considering the density of the product, this would correspond to a retention of 240 g/m^2. Thus the recommended dose of 300 ml/m^2 for curative treatment is acceptable.

- In order to demonstrate curative treatment against larvae of *Hylotrupes bajulus* in softwood, a study following EN 22 was presented. It should be noted that this standard has been retired in 2013, but older studies can be still considered acceptable. 81.2% mortality of larvae was found at the measured retention of 222.2 g/m^2. Considering the density of the product, this would correspond to an application rate of 278 ml/m^2. Thus the recommended dose of 300 ml/m^2 for curative treatment is acceptable.

- In order to demonstrate preventive treatment against *Reticulitermes grassei* (workers, soldiers and nymphs) in softwood, a valid study following EN 118 + EN 73 was presented. 100% mortality of termites was found at the measured retention of 198.2 g/m^2. Considering the density of the product, this corresponds to an application rate of 247.7 ml/m^2. Thus the recommended dose of 250 ml/m^2 for preventive treatment is acceptable.

- In order to demonstrate preventive treatment against *Reticulitermes spp* (workers, soldiers and nymphs) in softwood, a valid study following EN 117 + EN 73 was presented. The product was effective against termites at the mean measured retention of ≥14.4 Kg/m3, which was obtained with the application by vacuum/pressure process of 3% diluted product. This corresponds to a mean retention of ≥28.8 g/m^2 and an application rate of 36 ml/m^2. Thus the recommended dose of 250 ml/m^2 for preventive

treatment is acceptable.

It should be noted that in order to demonstrate curative treatment against *Reticulitermes spp* there is not a standard available, as indicated in the standard EN 14,128. However, the objective of curative products is, as for the preventive treatments against termites (tested following the standard EN 118 + EN 73), to protect wood against termites and to eliminate termites in the wood. Thus their function is not to destroy the entire colony (which is not in the wood). Moreover the target stages in the preventive and in the curative efficacy treatments are the same, which means that the expected doses of the biocidal active substance in both treatments would be the same. Therefore the efficacy demonstrated in the preventive efficacy tests (EN 117 and EN 118) can be extrapolated for a curative application.

- In order to demonstrate curative treatment against larvae of *Lyctus brunneus* in hardwood a study was presented following the standard Pr NF X41-665 developed by the FCBA (French Institute of Technology for Forest-based and Furniture Sectors). It is similar the old EN 273, which was withdrawn in 2013. The product was effective with a mean measured retention of 201.2 g/m^2. Considering the density of the product, this would correspond to an application rate of 251.5 ml/m^2. Thus the recommended dose of 300 ml/m2 for curative treatment is acceptable.

- In order to demonstrate curative treatment against larvae of *Anobium punctatum* a valid study following EN 48 was presented. The product was effective against common furniture beetles at the mean measured retention of 295.17 ml/m^2. Considering the density of the product, this would correspond to an application rate of 236.13 g/m^2. Thus the recommended dose of 300 ml/m^2 for curative treatment is acceptable.

In conclusion, CORPOL TRATAMIENTO DE MADERA ANTIXILOFAGOS has demonstrated its efficacy:

- for <u>preventive treatment</u> of wood by superficial application at the application of 250 ml/m2 against wood boring beetles (demonstrated in *Hylotrupes bajulus*) and subterranean termites (demonstrated in *Reticulitermes spp.*). The general claim against 'wood boring beetles' is accepted. It is accepted to mention *Hylotrupes bajulus* in the product label claims. The general claim against 'subterranean termites' is also accepted.

- for <u>curative treatment</u> of wood by superficial application at the application of 300 ml/m2 against wood boring beetles (demonstrated in *Hylotrupes bajulus*, *Lyctus brunneus*, *Anobium punctatum*) and subterranean termites (demonstrated in *Reticulitermes grassei*). The general claim against 'wood boring beetles' is accepted. It is accepted to mention *H. bajulus, L. brunneus* and *A. punctatum* in the product label claims. The general claim against 'subterranean termites' is also accepted.

Wood preservative for curative treatment against 'wood boring beetles' by <u>injection</u> application**:**

According to the guidance, the treatment by injection is neither considered superficial nor penetrating application. Since there is not standardisation of tests with application by injection, it is not mandatory to submit dedicated efficacy studies. The Applicant recommends the application by injection always as a complementary treatment to superficial application.
The application rate of superficial application, which has been demonstrated as effective in the former studies, is sufficient to accept the injection treatment as complementary

Therefore the efficacy assessment justified that CORPOL TRATAMIENTO DE MADERA ANTIXILOFAGOS meets the requirements for use in preservation of Use Class 1 wood.

Applicant intended uses included wood preservative treatment in UC2 in addition to UC1, however no study required for UC2 according EN 599-1 was submited. Therefore only UC1 can be granted.

2.2.5.6 Occurrence of resistance and resistance management

According to the revised literature, no reported cases of resistance or developing resistance have been found in wood-boring insects to wood preservatives with permethrin as active ingredient.

To ensure a satisfactory level of efficacy and avoid the development of resistance, the following recommendations have to be implemented:

- Always read the label or leaflet before use and follow all the instructions provided.
- The users should inform if the treatment is ineffective and report straightforward to the registration holder.

Effective Insecticide Resistance Management (IRM) strategies intend to minimise the resistance selective pressure within the populations to any type of insecticide. Alternations or rotations of insecticidal agents with different MoA groups provide a sustainable and effective approach to IRM in this sense.

In this line, IRAC (Insecticidal Resistance Action Committee) encourages producers to clearly indicate the IRAC MoA group number and description on the product label to assist users in the selection of insecticides for use in the rotations or alternations. Therefore, in addition to the detailed product information, a typical label should clearly indicate the IRAC MoA Group number & description, and minimal, brief advice on IRM.

2.2.5.7 Known limitations

There are not limitations known.

2.2.5.8 Evaluation of the label claims

The following matrix of categories and codes for product are applicable to CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS:

Table 2.2.5.1 Categories and codes for product CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS used for UC 1 wood

User category	General public/Professional users Trained professional users	A.10 A.30
Wood category	Softwood (preventive and curative)	B.10

	Hardwood (curative)	B.20
Wood product	Solid wood	C.10
Application aim	Preventive treatment- use class 1 Curative treatment / wood in service	D.40 D.50
Field of use	Use class 1 (preventive)	E.10
Method of application	Superficial application/brush treatment Superficial application/brush treatment + Injection Superficial application/spray treatment Superficial application/spray treatment + Injection	F.10 F.10+F.20 F.11 F.11+F.20
Target organisms	Wood boring beetles (preventive and curative) House longhorn beetle (preventive and curative) Common furniture beetle (curative) Powder post beetle (curative) Subterranean termites (genus) (preventive and curative)	G.30 G.31 G.32 G.33 G.51

2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

The product is not intended to be used with other products.

2.2.6 Risk assessment for human health

CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS contains one active substance, i.e. PERMETHRIN (0.35% w/w with a purity of minimum 93%) and other co-formulants.
No studies on the effects of CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS on human health have been submitted in the dossier of this biocidal product. However there are valid data available on each of the components in the mixture sufficient to allow the classification according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP Regulation). Active substance effects and critical concentrations are described in the permethrin assessment report (April 2014). Information on co-formulants are found on the ECHA dissemination website and the SDSs submitted. Therefore new studies with the biocidal product are scientifically not justified.

2.2.6.1 Assessment of effects on Human Health

There are not studies on the effects of CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS on human health submitted for this product. However there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). Therefore new studies with the biocidal product are scientifically not justified.

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS is neither corrosive nor irritant for the skin.

Justification for the value/conclusion	Based on the classification of the active substance and the coformulants and their respective content in the final formulation. None of the components of the product is classified for skin corrosion or irritation. Therefore, the product does not meet the criteria for classification for skin corrosion or irritation according to Regulation (EC) Nº 1272/2008. However, taking into account that some of the co-formulants are labelled as EUH066, an appropriate labelling for skin dryness and cracking is indicated.
Classification of the product according to CLP	No classification is required. Labelling with supplemental hazard statement EUH066: "Repeated exposure may cause skin dryness or cracking" is required.

Data waiving	
Information requirement	Skin corrosion/irritation study
Justification	The composition of the product is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. In addition, synergistic effects between any of the components are not expected. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008, therefore this study does not need to be conducted.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS is not an eye irritant.
Justification for the value/conclusion	Based on the classification of the active substance and the coformulants and their respective content in the final formulation. There are components classified as irritant to eyes with no specific classification limits. However, its concentration in the product does not exceed the limit for classification of the mixture (≥10%) according to Regulation (EC) Nº 1272/2008 thus the product is not classified as eye irritant.
Classification of the product according to CLP	No classification is required.

Data waiving	
Information requirement	Eye irritation study
Justification	The composition of the product is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. In addition, synergistic effects between any of the components are not expected. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008, therefore this study does not need to be conducted.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS is not a respiratory tract irritant
Justification for the conclusion	Based on the classification of permethrin and the different co-formulants and, their respective content in the final formulation. The biocidal product does not meet the criteria for classification for respiratory tract irritation according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classification is required.

Data waiving	
Information requirement	Respiratory tract irritation data.
Justification	No experimental data on respiratory tract irritation of the biocidal product is available. However, the composition of the product is known and there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS is not a skin sensitizer
Justification for the value/conclusion	Based on the classification of permethrin and the different co-formulants and, their respective content in the final formulation. Permethrin is classified for skin sensitisation according to annex VI of Regulation (EC) No 1272/2008. Since its concentration is below 1% but higher than 0.1% (threshold limit for elicitation), EUH208 should be required on the label.
Classification of the product according to CLP	Classification for skin sensitisation is not required. Labelling with EUH208: Contains permethrin. May produce an allergic reaction.

Data waiving	
Information requirement	Skin sensitization study.
Justification	For the biocidal product the composition is known. Sufficient data on the intrinsic properties of the components are available from safety data sheets and other information for each of the individual components in the product. In addition, synergistic effects between any of the components are not expected. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008, therefore this study does not need to be conducted.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS is not a respiratory sensitizer
Justification for the value/conclusion	Based on the classification of permethrin and the different co-formulants and, their respective content in the final formulation. None of the components of the product is classified for respiratory sensitization. Therefore, the product does not meet the criteria for classification for acute dermal toxicity according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classification is required.

Data waiving	
Information requirement	Respiratory sensitization data
Justification	For the biocidal product the composition is known. Sufficient data on the intrinsic properties of the components are available from safety data sheets and other information for each of the individual components in the product. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008. None of the ingredients are classified as respiratory sensitizers, so the product is not classified.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	DL50: >2000 mg/kg bw
Justification for the selected value	The classification of the biocidal product was conducted using endpoints included in Assessment Report (PT18) of permethrin and the SDSs of the other components. According to Assessment Report, the worst case acute oral LD50 for Permethrin is 480mg/kg bw. The calculated oral ATE for CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS is higher than 2000mg/kg bw. Therefore the product does not meet the criteria for classification for acute oral toxicity according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classification is required.

Data waiving	
Information requirement	Acute oral toxicity study
Justification	No studies have been performed with the biocidal product in order to avoid unnecessary testing with vertebrates. The composition of the product is known and there are valid data available on each of the

	components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected Therefore, this study does not need to be conducted.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	CL50: >5mg/l
Justification for the selected value	The classification of the biocidal product was conducted using endpoints included in Assessment Report of permethrin and the SDSs of the other components. According to Assessment Report, the worst case acute inhalation LC_{50} for Permethrin is 4.6mg/l. Some components of the product are classified for acute toxicity by inhalation route but are below their generic cut-off values (table 1.1. of CLP Regulation) hence they are not included in the calculation of the acute oral ATE (Acute Toxicity Estimate) of the biocidal product. The calculated inhalation ATE for CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS is higher than 5mg/l. Therefore the product does not meet the criteria for classification for acute inhalation toxicity according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classification is required.

Data waiving	
Information requirement	Acute inhalation toxicity study
Justification	No studies have been performed with the biocidal product in order to avoid unnecessary testing with vertebrates. The composition of the product is known and there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected Therefore, this study does not need to be conducted.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS is not classified for acute dermal toxicity
Justification for the selected value	Based on the classification of permethrin and the different co-formulants and, their respective content in the final formulation. None of the components of the product is classified for acute dermal toxicity. Therefore, the product does not meet the criteria for classification according to Regulation (EC) No 1272/2008.
Classification of the product	No classification is required.

according to CLP	

Data waiving	
Information requirement	Acute dermal toxicity study
Justification	No studies have been performed with the biocidal product in order to avoid unnecessary testing with vertebrates. The composition of the product is known and there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected Therefore, this study does not need to be conducted.

Specific target organ toxicity – single exposure

Narcotic effects

Value used in the Risk Assessment – STOT SE – Narcotic effects	
Value	CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS is classified as STOT SE – Narcotic effects (NE)
Justification for the selected value	Two components in the biocidal product are classified as STOT SE 3 - NE (H336). The sum of their concentrations in the product exceeds the limit for classification of the mixture (≥20%) according to Regulation (EC) Nº 1272/2008. Thus the product is classified as Specific Target Organ Toxicity - Single Exposure cat. 3 (Narcotic Effects) (H336).
Classification of the product according to CLP	STOT SE 3 - NE (H336)

Data waiving	
Information requirement	Specific target organ toxicity (single exposure) study
Justification	No studies have been performed with the biocidal product in order to avoid unnecessary testing with vertebrates. The composition of the product is known and there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected Therefore, this study does not need to be conducted.

Aspiration toxicity

Conclusion used in Risk Assessment – Aspiration toxicity	
Value/conclusion	CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS is not an aspiration toxicant

Justification for the value/conclusion	One component is classified as Asp. Tox. 1 (H304). Its concentration is >10% in the product and it has a kinematic viscosity <20.5 mm2/s. Therefore the product is classified as Asp. Tox. 1 (H304). However, according to Regulation (EC) No 1272/2008 (CLP). substances or mixtures classified in this hazard category need not be labelled for this hazard when placed on the market in aerosol containers or in containers fitted with a sealed spray attachment. Furthermore, the key to classifying these products is whether a pool of product is formed in the mouth, which then may be aspirated. If the mist or aerosol from a pressurised container is fine, a pool may not be formed. The mean diameter of aerosol particles population is 37.10 µm, so this hazard category can be discarded.
Classification of the product according to CLP	No classification is proposed.

Data waiving	
Information requirement	Aspiration toxicity study
Justification	No studies have been performed with the biocidal product in order to avoid unnecessary testing with vertebrates. The composition of the product is known and there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected Therefore, this study does not need to be conducted.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Permethrin
Value(s)	70%
Justification for the selected value(s)	Default value from EFSA guidance on dermal absorption for organic solvent-based dilution.(EFSA Journal 2017; 15(6):4873)

Data waiving	
Information requirement	Dermal absorption study
Justification	There is no experimental data available on the dermal absorption of CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS since no study has been conducted thus far. As a result, risk assessment calculations for human exposure have been made according to the EFSA guidance on dermal absorption (EFSA Journal, 2017;15(6):4873) using a default value of 70% dermal absorption for this product.

Endocrine disrupting properties

Endocrine disrupting properties assessment of active substance and co-formulants is mandatory from 7 June 2018, date when the Regulation (EU) 2017/2100 came into force, according to the article 19 of BPR.
According to the CAR and BPC Opinion (April 2014), permethrin is not considered to have endocrine disrupting properties. However, a comprehensive ED-assessment for the active substance and its metabolites according to Regulation (EU) 2017/2100 and the "Revised Guidance Document 150 on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption" will need to be performed at the renewal stage.
After examining the possible ED properties of co-formulants, several substances have been identified as having potential endocrine disrupting properties. If these substances are identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised.
Please, refer to the confidential annex for more information.

Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

The biocidal product CORPOL TRATAMIENTO DE MADERA ANTIXILOFAGOS contains one active substance and other coformulants. The active substance is permethrin (0.35% w/w).

Three non-active substances contained in the mixture are classified in terms of human health hazards. Two of them are in concentrations below the GCL or SCL for the hazard classes they are classified in. Thus they are not considered substances of concern.

The other substance (i.e. Hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, < 2% aromatics) is present in concentrations above the GCL or SCL for the hazard classes its is classified in. Thus it is considered a substance of concern.

Please see more information in the Confidential Annex.

According to Annex A of the document "Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 2.1 February 2017": a qualitative exposure and risk assessment should be done in order to determine whether S-phrases/P-statements normally associated with concerned R-phrases/H statements are sufficient or whether other risk mitigation measures should be applied. The qualitative risk assessment can be found in the section 2.2.6.3 Risk characterization for human health.

Available toxicological data relating to a mixture

There are not toxicological studies available conducted with the mixture.

2.2.6.2 Exposure assessment

The biocidal product CORPOL TRATAMIENTO MADERA ANTIXILÓFAGOS contains one active substance (permethrin 0.35% w/w) and other coformulants which could be substances of concern according to Guidance on BPR: Volume III Part B Risk Assessment Version 2.0 October 2015. Annex A: Substances of Concern – Proposed Human Health (Toxicology) Assessment Scheme for Authorisation of Biocidal Products.

One co-formulant substance (Hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, < 2% aromatics) is present in concentration which is above the GCL for the of Regulation (EC) 1272/2008 for the classes of STOT SE 3 (Narcotic effects) and Asp. Tox. 1. Thus it is considered a substance of concern assigned to BAND A, which means that associated evaluation/risk management requirements to reach safe situation are the application of P-statements associated with concerned H statements.

Active Substance: PERMETHRIN				
Value(s) used in the Risk Assessment				
Dermal absorption Value(s)	For Permethrin the dermal absorption for the exposure exposure and risk assessment should be the default value of 70%.			
Reference	**Study**	**NOAEL (LOAEL)**	**AF**	**Value**
AELshort-term	Rat 2 year oral study (acute effect) BAYER/SUMITOMO	59,43 mg/kg bw/day	100	0,5 mg/kg bw/day
AELmedium-term and AELlong-term	12-month dog study BAYER/SUMITOMO	5 mg/kg bw/day	100	0,05 mg/kg bw/day

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	Yes	Yes	Yes	No	No	Yes	No
Dermal	Yes	Yes	Yes	No	No	Yes	No
Oral	No	No	No	No	No	Yes	No

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	Vacuum-pressure application	Primary exposure. Vacuum treatment is intended to prevent the presence of woodworm and termite species in the wood. The spraying process is done by automated machines in hermetic closed tanks at indoor industrial premises without operator presence during the application.	Industrial (Trained-Professionals)

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group**
2.	Spraying application	Primary exposure. Spraying application is performed by the operator on the wood surfaces by a handheld or knapsack sprayer. The product is sprayed in indoor premises: parquet, flooring, wood decor (plinths, friezes, baseboards) and carpentry (doors and windows).	Trained-Professionals Professionals
3.	Brushing application	Primary exposure. This scenario of exposure may be occurring when the users apply the product over the wood by using a brush, in absence of general public.	Trained-Professionals Professionals
4.	Injection application	Primary exposure. The application by injection can be only applied by trained-professional and professional users as a curative treatment. The product is injected in the wood by means of a syringe.	Trained-Professionals Professionals
5.	Handling treated timber	Primary exposure. An adult who takes in contact with treated wood to move, cut or sand it. Considering the recommendation of the product's label, a safety-time of 12 hours must to be respected before to take contact with the treated wood.	Trained-Professionals Professionals
6.	Brushing application	Primary exposure. This scenario of exposure may be occurring when the users apply the product over the wood by using a brush.	Non-Professionals
7.	Handling treated timber	Primary exposure. An adult who takes in contact with treated wood to move, cut or sand it. Considering the recommendation of the product's label, a safety-time of 12 hours must to be respected before to take contact with the treated wood.	Non-Professionals
8.	Mixing and loading	Primary exposure. The fluid is delivered in a container and is decanted from containers that are manually handled.	Trained-professionals Professionals Non-Professionals
9	Cleaning brush equipment	Primary exposure, Washing out of a brush which has been used to apply the product.	Trained-professionals Professionals Non-Professionals
10.	Cutting and sanding	Secondary exposure. A trained-professional or a professional who takes in contact with dry treated wood to move, cutting or sanding it.	Trained Professionals, Professionals.
11.	Cutting and sanding	Secondary exposure. An adult who takes in contact with dry treated wood to move, cutting or sanding it.	Non-professionals

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group**
12.	Chewing wood off cut	Secondary exposure. Toddler who takes a piece of treated wood and chews it. Therefore, this secondary exposure is foreseeable by ingestion.	General public (toddler-acute)
13.	Playing and mouthing on weathered structure	Secondary exposure. This scenario is considered for toddler who play on weathered structures. Exposure is foreseeable by dermal and ingestion route.	General public (toddler-chronic)
14.	Inhalation residues indoors	Secondary exposure. This scenario is considered for the General public that stays in a premise where the wood has been treated with the biocide product.	General public
15.	Laundering contaminated work clothing	This scenario assumes that the laundering is undertaken in a domestic, automatic washing machine.	Trained-Professionals, Professionals.
16.	Laundering contaminated work clothing	This scenario assumes that the laundering is undertaken in a domestic, automatic washing machine.	Non-professionals.

Summary table: combined scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group**
Combined scenarios 3+5+8+9+ 15	Brushing + M&L + handling + cleaning brushes + laundering	Primary exposure Combined scenarios for application by brushing and rest of tasks of treatment.	Trained-Professionals, Professionals
Combined scenarios 3+4+5+8+9+15	Brushing + Injection + M&L + handling + cleaning brushes + laundering	Primary exposure Combined scenarios for application by brushing and injection and rest of tasks of treatment.	Trained-Professionals, Professionals
Combined scenarios 6+7+8+9+ 16	Brushing + M&L + handling + cleaning brushes + laundering	Primary exposure Combined scenarios for application by brushing and rest of tasks of treatment.	Non-Professionals

Primary exposure

Industrial exposure

One scenario have been considered for the exposure estimation during product application for industrial preventive treatment:

- Pressure process (vacuum-pressure)

Industrial processes are carried out in facilities with closed or confined areas made of materials resistant to the wood preservative product. Provisions are made for the collection, recycling and reuse of wood preservative collected from the conveyor or drip drying area. The release of wood preservatives from the treatment facility or from the

places where treated wood is stored into a surface water drain or a drain connected to a Wastewater Treatment Plant (STP) is not allowed.

Scenario [1]: **Industrial Vacuum pressure**

Description of Scenario [1]		
Vacuum pressure preventive treatment takes place in sealed chambers without operator's presence. Therefore, operators are dermally exposed through contact with contaminated equipment surfaces and through handling wet treated wood at the beginning or the end of the cycle treatment or by accidental contact with treated wood. In all cases, dermal exposed will be always over a short period (during the few minutes at the start and the few minutes at the end of the impregnation cycle). Following Recommendation 6 - Methods and models – version 4, Handling model 1 form TNsG 2002 User Guidance - Version 1 is carried out.		
	Parameters	Value
Tier 1	Hand exposure[1]	260 mg/cycle (inside gloves) 88.8 mg/cycle (75thpercentile TNsG 2002)
	Body exposure[1]	158 mg/cycle
	Inhalation[1]	0.6 mg/m3
	Duration[1]	3 cycles, 30 min.
	Dermal absortion Permethrin	70%
	Body weight[2]	60kg
	Inhalation rate[2]	1.25m^3/h
Tier 2	a) Coverall Permeation [3]	10%

[1] Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure
[2] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal products
[3] HEEG Opinion 9 Default protection factors for protective clothing and gloves. Impermeable coveralls.

Calculations for Scenario [1] **Vacuum pressure**

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from industrial uses					
Exposure scenario	**Tier / PPE**	**Active substance**	**Estimated inhal uptake mg/kg bw/d**	**Estimated dermal uptake mg/kg bw/d**	**Estimated total uptake mg/kg bw/d**
Scenario [1] Double Vacuum pressure	1	permethrin	2,19E-05	5,12E-02	5,12E-02
Scenario [1] Vacuum pressure	2a	permethrin	2,19E-05	3,38E-02	3,38E-02

Trained-Professional exposure

For ***in-situ treatments by trained professionals***, CORPOL TRATAMIENTO MADERAS ANTIXILÓFAGOS is intended to be used for treatment through the following methods:

- Spraying
- Brushing
- Injection

Scenario [2]: **Trained-professional spraying**

Description of Scenario [2]		
Spraying application is performed by the operator on the wood surfaces by a handheld or knapsack sprayer in absence of general public. Indoor application at premises like parquet, flooring, wood decor (plinths, friezes, baseboards) or carpentry (doors and windows) is considered a worse case for human exposure.. This task is developed for preventive treatments. Following the Biocides Human Health Exposure Methodology, to evaluate the operator exposure for the application method for trained-professionals, spraying model 2 of TNsG 2002, Part 2, has been chosen as the most similar scenario. This model is evaluated for indoor treatments The model includes the tasks for "mixing and loading" and "spray application" at a pressure from 4 to 7. bar.		
	Parameters	Value
Tier 1	Hands exposure[1]	273 (mg/min)
	Body exposure[1]	222 (mg/min)
	Inhalation[1]	76 (mg/m3)
	Duration[1]	90 minutes without distinction between the M&L and application phases.
	Dermal absorption permethrin	70%
	Body weight[2]	60kg
	Inhalation rate[2]	1.25m^3/h
Tier 2	Hands exposure[1] (inside gloves)	7.8 (mg/min)
Tier 3	Coverall Permeation[3]	10%
Tier 4	Coverall Permeation[3]	5%
Tier 5	Mask P3 Permeation[4]	10%

[1] Biocides Human Health Exposure Methodology

[2] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal products

[3] HEEG Opinion 9 Default protection factors for protective clothing and gloves. Impermeable coveralls.

[5] EN 529-2005

Calculations for Scenario [2]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from Spraying

Exposure scenario	Tier/PPE	Active substance	Estimated inhalation uptake mg/kg/d	Estimated dermal uptake mg/kg/d	Estimated total uptake mg/kg/d
Spraying	1 / No PPEs	permethrin	6,41E-03	1,39E+00	1,40E+00
Spraying	2 / Gloves	permethrin	6,41E-03	6,46E-01	6,52E-01
Spraying	3 / Gloves and coverall 10%	permethrin	6,41E-03	8,43E-02	9,08E-02
Spraying	4 / Gloves and coverall 5%	permethrin	6,41E-03	5,31E-02	5,95E-02
Spraying	5 / Gloves and coverall 5% and mask P3	permethrin	6,41E-04	5,31E-02	5,38E-02

Scenario [3]: **Trained-professional brushing**

Description of Scenario [5]		
In Trained-professioinal brushing scenario the user applies the product over the wood by using a brush in absence of general public. This task is developed for preventive or curative treatments. According to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure, following values are used in exposure assessment:		
	Parameters	Value
Tier 1	Hands exposure[1]	0.5417 (mg/m^2)
	Body exposure[1]	0.2382 (mg/m^2)
	Inhalation[1] non-volatile compounds	0.0016 (mg/m^2)
	Duration[1]	240 min
	Application area[1]	31.6 m^2
	Dermal absortion Permethrin	70%
	Body weight[2]	60kg
	Inhalation rate[2]	1.25m^3/h
Tier 2	Gloves permeation[3]	10%
Tier 3	Coverall permeation[3]	10%

[1] Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure and Biocides Human Health Exposure Methodology

[2] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal products

[3] HEEG Opinion 9 Default protection factors for protective clothing and gloves.

Calculations for Scenario [3]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from Brushing					
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake mg/kgbw/d**	**Estimated dermal uptake mg/kgbw/d**	**Estimated total uptake mg/kgbw/d**
Brushing	1	permethrin	1,47E-04	1,01E-01	1,01E-01
Brushing	2 / Gloves	permethrin	1,47E-04	3,77E-02	3,79E-02
Brushing	3 / Gloves and impermeable coverall	permethrin	1,47E-04	1,01E-02	1,02E-02

Scenario [4]: **Trained-professional Injection**

Description of Scenario [4]		
Injection curative scenario application methods, as requested for the applicant: injection application via filling of fligh holes by means of a syringe**.** According to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure, proposed model 29, following values are used in exposure assessment:		
	Parameters	Value
Tier 1	Hand exposure[1]	10 mg/loading
	Duration[1]	100 loadings
	Dermal absortion Permethrin	70%
	Body weight[2]	60kg
Tier2	Gloves permeation[3]	10%

[1] Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure

[2] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal products

[4] HEEG Opinion 9 Default protection factors for protective clothing and gloves.

Calculations for Scenario [4]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from Brushing					
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake mg/kgbw/d**	**Estimated dermal uptake mg/kgbw/d**	**Estimated total uptake mg/kgbw/d**
Injection	1	permethrin	-	4,08E-02	4,08E-02
Injection	2 / Gloves	permethrin	-	4,08E-03	4,08E-03

Scenario [5]: **Trained-professional Handling treated timber**

Description of Scenario [5]		
An adult who takes in contact with treated wood to move it. The wood is dryed and only dermal exposure is foreseeable. Curative treatment considers the highest dose application of 300 ml/m^2. According to HEEG Opinion 7, 2012 US EPA Standard Operating Procedure (SOPs) – Residential exposure assessment: 10.2.1 Section Post-Application Dermal Exposure Assessment, has been used for exposure assessment.		
	Parameters	Value
Tier 1	Exposure duration[1]	4 h
	Product density	0.765 mg/µl
	Percentage dislodgeable[1] (%)	10
	Transfer coefficient[2]	7,80E-01 m^2/h
	$F_{body}(S_{palms}/S_{body})$	2,4699E-02
	Active substance dermal absorption	70 %
	No PPE, clothing penetration	100%
Tier2	Gloves permeation[4]	10%

[1] HEEG Opinion 7, 2012 US EPA Standard Operating Procedure

[2] HEAdhoc Recommendation no. 12 New default values for indoor Transfer Coefficient

[3] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessments for biocidal products

[4] HEEG Opinion 9 Default protection factors for protective clothing and gloves.

Calculations for Scenario [5]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from Handling treated timber					
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake mg/kgbw/d**	**Estimated dermal uptake mg/kgbw/d**	**Estimated total uptake mg/kgbw/d**
Handling treated timber	1	permethrin	-	7,22E-02	7,22E-02
Handling treated timber	2 Gloves	permethrin	-	7,22E-03	7,22E-03

Combined scenarios

Combined exposures by same active substance by different tasks may occur. For this assessment, brushing + injection and handling treated timber for trained professionals and professionals are combined for active substance.

The result of the exposure assessment for this combination of scenarios is expecting to be the worst case of use of the product. For that reason, and taking into account no dose of

injection is provided for the applicant, we decide to calculate the maximum product dose of application by injection to reach the permethrin AEL using an reverse scenario.
It is important to note that the exposure by handling depends on the dose of product applied, but it is not the case for brushing and injection.

Table below shows results using the curative dose of 300ml/m^2 without taking into account the injection extra-dose:

Combined estimated exposure from professional uses				
Combined scenarios	**(Scenario) Tier/PPE**	**Systemic exposure Scenario (3)+(8)+(9) mg/kg/d**	**Systemic exposure Scenario (4) mg/kg/d**	**Systemic exposure Total mg/kg/d**
Brushing + Injection (3)+(8)+(9)+(4)	(3) Tier 2/Gloves+[(8)+(9)+(4)] Tier 1	4,35E-02	4,08E-02	8,43E-02
Brushing + Injection (3)+(8)+(9)+(4)	(3) Tier 3/Gloves and coverall+[(8)+(9)] Tier 1 +(4) Tier2 Gloves	1,58E-02	4,08E-03	1,62E-02

Combined estimated exposure from professional uses				
Combined scenarios	**(Scenario) Tier/PPE**	**Systemic exposure Scenario (3)+(8)+(9)+(4) mg/kg/d**	**Systemic exposure Scenario (5) mg/kg/d**	**Systemic exposure Total mg/kg/d**
Brushing + Injection (3)+(8)+(9)+(4) + Handling (5)	(3) Tier 2/Gloves+[(8)+(9)+(4)] Tier 1 + (5) Tier 2/Gloves	8,43E-02	7,22E-03	9,15E-02

Mantaining the Scenario exposure (brushing+injection) (1,62E-02 mg/kg/d) and assuming that total Scenario exposure (brushing + injection + handling) that is the necessary to reach the permethrin AEL (0.05 mg/kg/d), the handling exposure results in 3,38E-02 mg/kg/d.
Using this value as maximum exposure of handling and developing a reverse scenario, we obtain the value os 1,40E+00 l/m^2 for maximum application product dose to reach the Permethrin AEL.
As the brusing dose for curative treatment is 3.00E-01 l/m^2, the maximum injection dose to reach the permethrin AEL for this combined scenario is 1,10E+00 l/m^2.
See Annex 3.2.
From this point, to calculate the exposure for the rest of scenarios, the maximum injection dose will be used as a worst case when necessary.
For clarity and well-understanding, a maximuun injection dose of 1000 ml/m^2 will be recommended to users on the label.

Table below shows results using the curative dose of 1400ml/m^2 taking into account the injection extra-dose:

Combined estimated exposure from professional uses				
Combined scenarios	**(Scenario) Tier/PPE**	**Systemic exposure Scenario (3)+(8)+(9)+(4) mg/kg/d**	**Systemic exposure Scenario (5) mg/kg/d**	**Systemic exposure Total mg/kg/d**
Brushing + Injection (3)+(8)+(9)+(4) + Handling (5)	(3) Tier 2/Gloves+[(8)+(9)+(4)] Tier 1 + (5) Tier 2/Gloves	8,43E-02	3,38E-02	1,18E-01
Brushing + Injection (3)+(8)+(9)+(4) + Handling (5)	((3) Tier 3/Gloves and coverall)+[(8)+(9)] Tier 1 +(4) Tier2 Gloves + (5) Tier 2/Gloves	1,62E-02	3,38E-02	5,00E-02

Professional exposure

For ***in-situ treatments by professionals***, CORPOL TRATAMIENTO MADERAS ANTIXILÓFAGOS is intended to be used for treatment through the following methods:

- Spraying
- Brushing
- Injection

Due to the particular spanish trained professional and professional users definition:

- Trained professional users (TP): pest control operators, having received specific training in biocidal product uses according to the national legislation in force.
- Professional users (NTP): professionals that use the biocidal products in the context of his profession, that is not pest control operator, and that are unlikely to have received any specific training in biocidal product use according to the national legislation in force. It can be expected that they have some knowledge and skills handling chemicals (if they must use it in their job) and they are able to use correctly some kind of PPE if necessary.

At the same time, there are also some restrictions of packaging in relation to those user categories and product types.

In the case of product CORPOL TRATAMIENTO MADERA ANTIXILÓFAGOS the assessment exposure for trained professional users is considered adequated for professionals and no new evaluation is necessary.

Non-professional exposure

For ***in-situ treatments by non-professionals***, CORPOL TRATAMIENTO MADERAS ANTIXILÓFAGOS is intended to be used for treatment through the following methods:

- Brushing
- Injection for curative treatment complementary to brushing. The injection is understood as the product introduced into the insect holes with the help of a brush and it is not separately evaluated because it is consider cover by brushing exposure assessment.

Scenario [6]: **Non-professional brushing**

Description of Scenario [6]		
In Non-professioinal brushing scenario, the user applies the product over the wood by using a brush. This task is developed for preventive or curative treatments. According to Recommendation no. 10 of the BPC Ad hoc Working Group on Human Exposure, following values are used in exposure assessment:		
	Parameters	Value
Tier 1	Hands exposure[1]	1.7 µl/min
	Body exposure[1]	1.12 µl/min
	Inhalation[1] non-volatile compounds	1.63 mg/m^3
	Duration[1]	120 min
	Application area[1]	31.6 m^2
	Dermal absortion Permethrin	70%
	Body weight[2]	60kg
	Inhalation rate[2]	1.25m^3/h

[1] Recommendation no. 10 of the BPC Ad hoc Working Group: The most appropriate model to be used for the scenario of non-professional application of paints by brushing and rolling.

[2] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal products.

Calculations for Scenario [6]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from Non-professional Brushing					
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake mg/kgbw/d**	**Estimated dermal uptake mg/kgbw/d**	**Estimated total uptake mg/kgbw/d**
Brushing	1	permethrin	2,38E-04	3,85E-02	3,87E-02

Scenario [7]: **Non-professional Handling treated timber**

Description of Scenario [7]
An adult who takes in contact with treated wood to move it. The wood is dryed and only dermal exposure is foreseeable. Curative treatment considers the highest dose application calculated to reach the permethrin AEL of 1400 ml/m^2. According to HEEG Opinion 7, 2012 US EPA Standard Operating Procedure (SOPs) – Residential exposure assessment: 10.2.1 Section Post-Application Dermal Exposure Assessment, has been used for exposure assessment.

	Parameters	Value
Tier 1	Exposure duration[1]	1 h
	Product density	0.765 mg/µl
	Percentage dislodgeable[1] (%)	10
	Transfer coefficient[2]	7,80E-01 m^2/h
	$F_{body}(S_{palms}/S_{body})$	2,4699E-02
	Active substance dermal absorption	70 %
	No PPE, clothing penetration	100%

[1] HEEG Opinion 7, 2012 US EPA Standard Operating Procedure

[2] HEAdhoc Recommendation no. 12 New default values for indoor Transfer Coefficient

[3] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessments for biocidal products

[4] HEEG Opinion 9 Default protection factors for protective clothing and gloves.

Calculations for Scenario [7]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from Handling treated timber					
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake mg/kgbw/d**	**Estimated dermal uptake mg/kgbw/d**	**Estimated total uptake mg/kgbw/d**
Handling treated timber	1	permethrin	-	8,45E-02	8,45E-02

Scenario [8]: **Mixing and Loading**

Description of Scenario [8]		
The fluid is delivered in a container and is decanted from containers that are manually handled. This task is done by professionals where they are exposed during the mixing and loading operations during manual or automated addition. According to HEEG Opinion 1, on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale, Mixing & loading model 7-TNsG part 2 p.142 (corrected), has been used to calculate the exposure due to liquid manual loading/pouring application for this scenario.		
	Parameters	Value
Tier 1	Dermal exposure under clothes and gloves[1]	1.01 mg/min
	Inhalation exposure[1]	0.94 mg/m3
	Duration[1]	10 min
	Dermal absortion Permethrin	70%
	Body weight[2]	60kg

	Inhalation rate[2]	1.25m^3/h

[1] HEEG opinion 1 on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale.

[2] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal products

Calculations for Scenario [8]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from Mixing and Loading					
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake mg/kg/d**	**Estimated dermal uptake mg/kg/d**	**Estimated total uptake mg/kg/d**
Mixing and Loading	1 Gloves and clothes	Permethrin	1,10E-03	4,12E-04	1,51E-03

Scenario [9]: **Wash out of brushes**

Description of Scenario 9		
A post-application task which may lead to some degree of exposure is cleaning the brush used to apply the product. Brush cleaning can be expected to last for no more than 15 minutes and might result in some exposure to hands. To calculate the exposure due to whashing out brushes, the HEEG opinion 11 and its computerised calculator have been used. Cleaning the brush used for applying paint may be done by repeated dipping and swilling it in a vessel containing an appropriate solvent. A large brush might have a size of 10 x 10 x 2 cm, corresponding to a volume of 200 ml. It is assumed that after painting one eighth (1/8) of the brush volume is paint. Cleaning is assumed to be done in three steps, each time using fresh solvent. The volume at each step should be large enough to allow a sufficient dilution of the residues in the brush. For a brush having a volume of 200 ml the volume of the cleaning solvent would be at least 400 ml per step. Each washing step is assumed to result in an approximately 10-fold dilution of the residues in the brush (i.e. 10 % of the paint originally on the brush remains after one washing). After each step the brush is assumed to be squeezed by the hand to get rid of as much solvent as possible. It is assumed that with this step 50% of the solution in the washed brush is released and may potentially contaminate the hand. However, it is further assumed that the squeezing is not done by the bare hand but rather by wrapping it first with a cleaning rag, which absorbs 90% of the released liquid. It is assumed the brush is washed and squeezed for a maximum of 3 times. During brush cleaning, professionals may retain gloves worn during brush application of the product (Tier 2 assessment). No exposure of areas of the body other than the hands is assumed to occur; and exposure via inhalation is considered negligible.		
	Parameters	Value
Tier 1	Body weight[2]	60 kg
	Brush size	200 ml

	Volume of residual solution in brush	1/8 of brush volume = 25 ml
	Volume of each washing solution[1]	400 ml
	Remaining residues in brush after each washing step[1]	10%
	Remaining residues in brush after each squeezing[1]	50%
	Penetration through cleaning cloth during squeezing[1]	10%
	Dermal absorption Permethrin	70%
Tier 2	Gloves	90% protection

[1] HEEG opinion 11 - Exposure model Primary exposure scenario – washing out of a brush which has been used to apply a paint (TM III 2010)

[2] HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017)

Calculations for Scenario [9]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from Washing out brushes					
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake**	**Estimated dermal uptake mg/kg bw/d**	**Estimated total uptake mg/kg bw/d**
Washing out brushes	1	Permethrin	-	4,11E-03	4,11E-03
Washing out brushes	2 Gloves	Permethrin	-	4,11E-04	4,11E-04

Combined scenarios

Combined exposures by same active substance by different tasks may occur. For this assessment, brushing, mixing and loading, cleaning brushes and handling treated timber for non-professionals are combined for active substance.

Combined estimated exposure from professional uses				
Combined scenarios	**(Scenario) Tier/PPE**	**Systemic exposure Scenario 6+8+9 mg/kg/d**	**Systemic exposure Scenario 7 mg/kg/d**	**Systemic exposure Total mg/kg/d**
6+8+9+7 Brushing + M& L + cleaning brushes + handling	Tier 1 no PPEs	4,43E-02	8,45E-02	1,29E-01

Secondary Exposure

Exposure of the general public

Preserved wood is not placed on the market until the product is dry. The product is suitable for indoor or outdoor use. The reference scenarios modelled are as follows:

- Acute phase reference scenarios
  - Adult cutting and sanding treated wood -inhalation and dermal route.
  - Infant acute chewing wood off-cut -ingestion route.
- Chronic phase reference scenarios
  - Adult inhalation of volatilised residues indoors - inhalation route.
  - Adult laundering work clothes at home - dermal route.
  - Child playing on playground structure outdoors - dermal route.
  - Infant playing on weathered structure and mouthing route. - dermal and ingestion

Indirect exposure via the environment is considered to be of minor importance as the release to the environment is limited.

Scenario [10]: Professional sanding treated wood. Curative

Description of Scenario [10]		
The scenario is described in the TNsG on Human Exposure to Biocidal Products Part 3, p50-51 as revised by User Guidance version 1 p50-54 (EC, 2002a).		
	Parameters	Value
Tier 1	Volume of wood to be sanded in 1h	4,00E+03 cm^3
	Rate of product absorbed in wood	1400 ml/m^2
	Product density	0.765 g/ml
	Wood density	0.4 g/ml
	Dust concentration in air (occupational exposure limit for wood dust)	5 mg/m^3
	Inhalation rate[2]	1.25 m^3/h
	Exposure duration	6 h
	Body weight[2]	60 kg
	Percentage dislodgeable[3]	2%
	Hand surface[2]	420 cm^2
	Transfer to hands	20%

[1] TNsG on Human Exposure to Biocidal Products Part 3, p50-51 as revised by User Guidance version 1 p50-54 (EC, 2002a)

[2]HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal products

[3] *Biocides Human Health Exposure Methodology* 2015, p. 181.

Calculations for Scenario [10]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake mg/kg/d**	**Estimated dermal uptake mg/kg/d**	**Estimated oral uptake**	**Estimated total uptake mg/kg/d**
Scenario 10	Tier 1 /NO PPE	5,92E-04	7,37E-03	-	7,96E-03

Scenario [11]: Non-Professional sanding treated wood. Curative

Description of Scenario [11]		
The scenario is described in the TNsG on Human Exposure to Biocidal Products Part 3, p50-51 as revised by User Guidance version 1 p54-57 (EC, 2002a).		
	Parameters	Value
Tier 1	Volume of wood to be sanded in 1h	4,00E+03 cm^3
	Rate of product absorbed in wood	1400 ml/m^2
	Product density	0.765 g/ml
	Wood density	0.4 g/ml
	Dust concentration in air (occupational exposure limit for wood dust)	5 mg/m^3
	Inhalation rate[2]	1.25 m^3/h
	Exposure duration	1 h
	Body weight[2]	60 kg
	Percentage dislodgeable[3]	2%
	Hand surface[2]	420 cm^2
	Transfer to hands	20%

[1] TNsG on Human Exposure to Biocidal Products Part 3, p50-51 as revised by User Guidance version 1 p50-54 (EC, 2002a)

[2]HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal products

[3] *Biocides Human Health Exposure Methodology* 2015, p. 181.

Calculations for Scenario [11]

Summary table: estimated exposure from non-professional users					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake mg/kg/d**	**Estimated dermal uptake mg/kg/d**	**Estimated oral uptake**	**Estimated total uptake mg/kg/d**
Scenario 11	Tier 1 /NO PPE	9,86E-05	7,37E-03	-	7,46E-03

Scenario [12]: Toddler chewing a piece of wood. Curative

Description of Scenario [12]		
This scenario is described in the TNsG on Human Exposure to Biocidal Products Part 3, p50-51 as revised by User Guidance version 1 p54-57 (EC, 2002a). See Annex 3.2. for exposure calculations.		
	Parameters	Value
Tier 1	Application rate	1400 ml/m^2
	Extraction by chewing[1]	10%
	Size of wood composites chip[1]	16cm^3
	Surface of wood composite chip treated[1]	16cm^2
	Oral absorption	100%
	Body weight[2]	10 kg

[1] TNsG on Human Exposure to Biocidal Products Part 3, p42 as revised by User Guidance version 1 p50-54 (EC, 2002a
[2]HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal products

Calculations for Scenario [12]

Summary table: estimated exposure fof toddler					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake mg/kg/d**	**Estimated dermal uptake mg/kg/d**	**Estimated oral uptake**	**Estimated total uptake mg/kg/d**
Scenario 12	Tier 1 /NO PPE	-	-	6,01E-02	6,01E-02

Scenario [13]: Toddler playing and mouthing on playground weathered wood structure outdoors

Description of Scenario [13]
This secondary exposure scenario is based on TNsG 2002, v1 and on the HEAdhoc Recommendation no. 5 (2015). In this scenario, during playing on timber wheathered structure, dermal as well as oral (through hand-to-mouth transfer) exposure is considered.

Description of Scenario [13]		
Tier 1	Parameters	Value
	Application rate	1400 ml/m^2
	Contact surface (hands)[1]	2,31E+02 cm^2
	Hands Contaminated area (%)[2]	20%
	Dislogeable fraction (%)[3]	2%
	Dermal absortion	70%
	Transferable coefficient of dried paint from hand to mouth[4]	50%
	Oral absortion	100%
	Body weight[1]	10 kg

1 HEAdhoc Recommendation no. 14

2 TNsG, 2002, v1, part 3, p 51

3 TNsG, 2002, v1, part 2, p 204 (rough sawn wood-dried fluid)

4 Recommendation no 5 (Consexpo. Pest Control Fact Sheet, 2006; section 2.2.7 "Parameters for hand-mouth contact")

Calculations for Scenario [13]

Summary table: estimated exposure for toddler					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake mg/kg/d**	**Estimated dermal uptake mg/kg/d**	**Estimated oral uptake**	**Estimated total uptake mg/kg/d**
Scenario 13	Tier 1 /NO PPE	-	1,16E-02	1,66E-02	2,83E-02

Scenario [14]: General public - Inhalation volatilised residues indoors

Description of Scenario [14]
The exposure assessment due to this scenario has been carried out according to HEEG Opinion 13. As a Tier-1 screening tool whether inhalation exposure can be neglected or should be included into the risk assessment, the following screening test which is based on the toddler representing the worst case is proposed for each active substance: Let mw and vp denote the molecular weight (in g/mol) and the vapour pressure (in Pa).For toddler (based on an inhalation rate of 8 m^3/24 hr and bw of 10 kg) and using an AEL in mg a.s./kg bw/d, if: $$0.328 \frac{mw\ vp}{AEL_{long\text{-}term}} \leq 1$$ then risk from inhalation exposure for the toddler is negligible, otherwise inhalation exposure should be included in the risk assessment. If the inhalation risk for the toddler is negligible then the inhalation risk for the

Description of Scenario [14]
infant, child and for the adult can also beconsidered to be negligible. For the product, there is one active substance:

Active substance	Vapour pressure a.s.	Molecular weight a.s.	AEL $_{long\ term}$ (mg a.s./kg/bw/d)	Constant	Result	**Negligible / Included**
Permethrin	2,16E-06	391,29	0,05	0,328	1,26E-02	negligible

Scenario [15]: Professionals Laundering work clothes

Description of Scenario [15]
Exposure to product can occur when washing contaminated work clothes. Persons at risk are adults professionals. The exposure is considered acute intermediary, as it does not occur on a daily basis but may be longer-term. In general, this approach assumes that the washing is carried out in a domestic automatic washing machine, therefore, the exposure will be dermally through the hands, from handling the contaminated clothes before and during the introduction of the clothes in the washing machine. Laundering is considered to be after a five day work week, hence the total amount of product on work clothes is assumed to be five times the daily contamination associated with the application method used and it is assumed that the clothing to be washed is a coverall worn by a trained professional. The contamination of clothes is based on the professional spraying from which the tier that shows safe use is tier 2 using gloves. It is assumed that applicator wear impermeable coverall which, according to HEEG opinion 9, have a Default Protection Factor of 90%.

	Parameters	Value
Tier 1	Indicative value of body from model[1] mg	7,53
	Impermeable coverall penetration[3]	10%
	Surface medium-sized coverall[4] cm^2	22700

[1] Consumer spraying and dusting model 2 TNsG part 2, p 197.
[3] HEEG opinion 9
[4] Estimated parameter usually accepted

Calculations for Scenario [15]

Summary table: estimated exposure for professionals					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake mg/kg/d**	**Estimated dermal uptake mg/kg/d**	**Estimated oral uptake**	**Estimated total uptake mg/kg/d**
Scenario 15	Tier 1 /NO GLOVES	-	3,00E-05	-	3,00E-05

Scenario [16]: Non-Professionals Laundering work clothes

Description of Scenario [16]		
Exposure to product can occur when washing contaminated work clothes. Persons at risk are adults non-professionals. The exposure is considered acute intermediary, as it does not occur on a daily basis but may be longer-term. In general, this approach assumes that the washing is carried out in a domestic automatic washing machine, therefore, the exposure will be dermally through the hands, from handling the contaminated clothes before and during the introduction of the clothes in the washing machine. Laundering is considered to be after one day work contamination associated with the application method used and it is assumed that the clothing to be washed are regular clothes which, according to HEEG opinion 9, have a Default Protection Factor of 50%.		
	Parameters	Value
Tier 1	Indicative value of scenario brushing mg	1,03E+02
	Regualr clothes penetration[1]	50%
	Surface medium-sized coverall[2] cm^2	22700

[1] HEEG opinion 9
[2] Estimated parameter usually accepted

Calculations for Scenario [16]

Summary table: estimated exposure for professionals					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake mg/kg/d**	**Estimated dermal uptake mg/kg/d**	**Estimated oral uptake**	**Estimated total uptake mg/kg/d**
Scenario 16	Tier 1 /NO GLOVES	-	4,55E-05	-	4,55E-05

Combined scenarios

Combined exposures by same active substance by different tasks may occur. For this assessment, brushing, mixing and loading, cleaning brushes, handling treated timber and laundering clothes are combined for active substance.

	Combined estimated exposure				
Users	**Combined scenarios**	**(Scenario) Tier/PPE**	**Systemic exposure Scenario 3+8+9+4+5 mg/kg/d**	**Systemic exposure Scenario 15 mg/kg/d**	**Systemic exposure Total mg/kg/d**

Trained professionals	Brushing + M& L + cleaning brushes + Injection (3)+(8)+(9)+(4) + Handling (5)+ Laundering (15)	(3) Tier 2/Gloves+[(8)+(9)+(4)] Tier 1 + (5) Tier 2/Gloves+ (15) Tier1	1,18E-01	3,00E-05	3,98E-02
Trained professionals	Brushing + M& L + cleaning brushes + Injection (3)+(8)+(9)+(4) + Handling (5))+ Laundering (15)	((3) Tier 3/Gloves and coverall+[(8)+(9)] Tier 1 +(4) Tier2 Gloves + (5) Tier 2/Gloves + (15) Tier1	5,00E-02	3,00E-05	1,59E-02
Users	**Combined scenarios**	**(Scenario) Tier/PPE**	**Systemic exposure Scenario 6+8+9+7 mg/kg/d**	**Systemic exposure Scenario 16 mg/kg/d**	**Systemic exposure Total mg/kg/d**
Non-professionals	Brushing + M& L + cleaning brushes + handling (6)+(8)+(9)+(7)+ Laundering(16)	Tier 1 no PPEs	1,29E-01	4,55E-05	4,44E-02

Monitoring data

No monitoring studies have been performed with the formulated product as they are not considered necessary.

Dietary exposure

Indirect exposure via food, drinking water or livestoke can be excluded when the product is applied according to the recommended uses of CORPOL TRATAMIENTO MADERA ANTIXILÓFAGOS.

Additionally, the following RMMs are applied to exclude contact with food and feedstuff;

- "Do not use on wood which may come in direct contact with food, feeding stuff and livestock animals"

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/day)**

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/day)**
1 Vacuum-pressure application	Industrial (Trained Professionals)	Tier 2 / PPE (Gloves and impermeable coverall)	3,38E-02
2 Spraying	Trained Professionals, Professionals	Tier 5 / PPE (Gloves, coated coverall and mask)	5,38E-02
3 Brushing	Trained Professionals, Professionals	Tier 3 / PPE (Gloves and impermeable coverall)	1,02E-02
4 Injection	Trained Professionals, Professionals	Tier 2 / PPE (Gloves)	4,08E-03
5 Handling	Trained Professionals, Professionals	Tier 2 / PPE (Gloves)	7,22E-03
3+4+8+9 Brushing + Injection +M&L + cleaning brushes	Trained Professionals, Professionals	(3) Tier 3/Gloves and impermeable coverall+[(8)+(9)] Tier 1 +(4) Tier2 Gloves	1,62E-02
3+4+5+8+9 Brushing + Injection + M&L + handling + cleaning brushes	Trained Professionals, Professionals	((3) Tier 3/Gloves and impermeable coverall+[(8)+(9)] Tier 1 +(4) Tier2 Gloves + (5) Tier 2/Gloves	5,00E-02
6 Brushing application	Non-Professional	No PPE	3,87E-02
7 Handling treated timber	Non-Professional	No PPE	8,45E-02
8 Mixing and loading	Trained Professionals, Professionals Non-Professional	No PPE	1,51E-03
9 Cleaning brush equipment	Trained Professionals, Professionals Non-Professional	No PPE	4,11E-03
6+7+8+9 Brushing + M&L + handling + cleaning brushes	Non-Professionals	No PPE	1,29E-01
10 Cutting and sanding	Trained Professionals, Professionals	No PPE	7,96E-03
11 Cutting and sanding	Non-Professionals	No PPE	7,46E-03

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/day)**
12 Chewing wood off cut	General Public. Toddler	No PPE	6,01E-02
13 Playing and mouthing on weathered structure	General Public. Toddler	No PPE	2,83E-02
14 Inhalation residues indoors	General public	No PPE	Negligible
15 Laundering contaminated work clothing	Trained Professionals, Professionals	No PPE	3,00E-05
16 Laundering contaminated work clothing	Non-professionals	No PPE	4,55E-05

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Active Substance: PERMETHRIN				
Value(s) used in the Risk Assessment – Dermal absorption				
Value(s)	For Permethrin the dermal absorption for the exposure exposure and risk assessment should be the default value of 70%.			
Value(s) used in the Risk Assessment – AEL				
Reference	**Study**	**NOAEL (LOAEL)**	**AF**	**Value**
$AEL_{short\text{-}term}$	Rat 2 year oral study (acute effect) BAYER/SUMITOMO	59,43 mg/kg bw/day	100	0,5 mg/kg bw/day
$AEL_{medium\text{-}term}$ and $AEL_{long\text{-}term}$	12-month dog study	5 mg/kg bw/day	100	0,05 mg/kg bw/day
ARfD	2-year rat toxicity study	NOAEL = 50 mg/kg bw/d	100	0.5
ADI	1-year dog study	NOAEL = 5 mg/kg bw/d	100	0.05

Maximum residue limits or equivalent

MRLs or other relevant	Reference	Relevant commodities	Value

reference values			
MRL	EU Reg. 396/2005 (PPP)	All commodities	Cf: Reg. (EU) 2017/623
	EU Reg. 470/2009 (VMP)	Food of animal origin (bovine)	Cf: Reg (EU) 37/2010

PPP: plant protection product
VMP: veterinary medicinal product

As the product is to be used for preventive and curative treatment of interior woods that do not come in direct contact with food and feedstuff, the existing MRLs are not expected to be exceeded.

Primary Exposure

2.2.6.1.1 Risk for industrial users

Scenario [1] Industrial Vacuum-pressure

Scenario	**Tier**	**$AEL_{long-term}$ mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/AEL (%)**	**Acceptable (yes/no)**
Vacuum-pressure / Scenario 1	Tier 1 / NO PPE	0.05	5,12E-02	1,02E+02	No
Vacuum-pressure application/ Scenario 1	Tier 2 / PPE (gloves + impermeable coverall 10%)	0.05	3,38E-02	6,76E+01	Yes

2.2.6.1.2 Risk for Trained-professional users

Scenario [2] Trained-professional spraying

Scenario	**Tier**	**$AEL_{long-term}$ mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/AEL (%)**	**Acceptable (yes/no)**
Scenario [2] Trained-professional spraying	1 No PPEs	0.05	1,40E+00	2,80E+03	No
Scenario [2] Trained-professional spraying	2 Gloves	0.05	6,52E-01	1,30E+03	No
Scenario [2] Trained-professional spraying	3 Gloves and coverall 10%	0.05	9,08E-02	1,82E+02	No
Scenario [2] Trained-	4 Gloves and coverall 5%	0.05	5,95E-02	1,19E+02	No

professional spraying					
Scenario [2] Trained-professional spraying	5 Gloves and coverall 5% and mask P3	0.05	5,38E-02	1,08E+02	No

Scenario [3]: Trained-professional brushing

Scenario	Tier	$AEL_{long-term}$ mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/AEL (%)	Acceptable (yes/no)
Brushing	1	0.05	1,01E-01	2,02E+02	No
Brushing	2 Gloves	0.05	3,79E-02	7,57E+01	Yes
Brushing	3 Gloves and impermeable coverall	0.05	1,02E-02	2,04E+01	Yes

Scenario [4]: Trained-professional Injection

Scenario	Tier	$AEL_{long-term}$ mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/AEL (%)	Acceptable (yes/no)
Injection	1	0.05	4,08E-02	81.67	Yes
Injection	2 Gloves	0.05	4,08E-03	8.17	Yes

Scenario [5]: Trained-professional Handling treated timber

Scenario	Tier	$AEL_{long-term}$ mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/AEL (%)	Acceptable (yes/no)
Handling treated timber	1	0.05	7,22E-02	1,44E+02	No
Handling treated timber	2 Gloves	0.05	7,22E-03	1,44E+01	Yes

Table below shows results using the curative dose of 1400ml/m^2 taking into account the injection extra-dose permethrin calculated to reach the AEL in combinated scenarios:

Scenario	Tier	$AEL_{long-term}$ mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/AEL (%)	Acceptable (yes/no)
Handling treated timber	2 Gloves	0.05	3,38E-02	6,76E+01	Yes

2.2.6.1.3 Risk for Professional users

For ***in-situ treatments by professionals***, CORPOL TRATAMIENTO MADERAS ANTIXILÓFAGOS is intended to be used for treatment through the following methods:

- Spraying
- Brushing
- Injection

Due to the particular sapanish trained professional and professional users definition:

- Trained professional users (TP): pest control operators, having received specific training in biocidal product uses according to the national legislation in force.
- Professional users (NTP): professionals that use the biocidal products in the context of his profession, that is not pest control operator, and that are unlikely to have received any specific training in biocidal product use according to the national legislation in force. It can be expected that they have some knowledge and skills handling chemicals (if they must use it in their job) and they are able to use correctly some kind of PPE if necessary.

At the same time, there are also some restrictions of packaging in relation to those user categories and product types.

In the case of product CORPOL TRATAMIENTO MADERA ANTIXILÓFAGOS the risk characterisation for trained professional users is considered adequate for professionals and no new evaluation is necessary.

2.2.6.1.4 Risk for Non-professiional users

Scenario [6]: Non-professional brushing

Scenario	Tier	$AEL_{long-term}$ mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/AEL (%)	Acceptable (yes/no)
Brushing	1	0.05	3,87E-02	7,74	Yes

Scenario [7]: Non-professional Handling treated timber

Table below shows results using the curative dose of 1400ml/m^2 taking into account the injection extra-dose permethrin calculated to reach the AEL in combinated scenarios:

Scenario	Tier	$AEL_{long-term}$ mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/AEL (%)	Acceptable (yes/no)
Handling treated timber	1	0.05	8,45E-02	1,69E+00	Yes

Scenario [8]: Mixing and Loading

Scenario	Tier	$AEL_{long-term}$ mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/AEL (%)	Acceptable (yes/no)
Mixing and Loading	1 Gloves and clothes	0.05	1,51E-03	0,30	Yes

Scenario [9]: Wash out of brushes

Scenario	Tier	$AEL_{long-term}$ mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/AEL (%)	Acceptable (yes/no)
Washing out brushes	1	0.05	4,11E-03	0,82	Yes
Washing out brushes	2 Gloves	0.05	4,11E-04	0.08	Yes

Secondary Exposure

2.2.6.1.5 Risk for General public

Scenario [10]: Professional sanding treated wood. Curative

Table below shows results using the curative dose of 1400ml/m^2 taking into account the injection extra-dose permethrin calculated to reach the AEL in combinated scenarios:

Scenario	Tier	$AEL_{long-term}$ mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/AEL (%)	Acceptable (yes/no)
Professional sanding treated wood	1 /NO PPE	0.05	7,96E-03	1,59E+01	Yes

Scenario [11]: Non-Professional sanding treated wood. Curative

Scenario	Tier	$AEL_{long-term}$ mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/AEL (%)	Acceptable (yes/no)
Non-Professional sanding treated wood	1 /NO PPE	0.05	7,46E-03	1,49E+00	Yes

Scenario [12]: Toddler chewing a piece of wood. Curative

Scenario	Tier	$AEL_{long-term}$ mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/AEL (%)	Acceptable (yes/no)
Toddler chewing a piece of wood	1 /NO PPE	0.05	6,01E-02	1,20E+01	Yes

Scenario [13]: Toddler playing and mouthing on playground weathered wood structure outdoors

Scenario	Tier	$AEL_{long-term}$ mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/AEL (%)	Acceptable (yes/no)
Toddler playing and mouthing on	1 /NO PPE	0.05	2,83E-02	5,66E+01	Yes

playground weathered wood structure outdoors					

Scenario [14]: General public - Inhalation volatilised residues indoors

Negligible

Scenario [15]: Professionals Laundering work clothes

Scenario	Tier	$AEL_{long-term}$ mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/AEL (%)	Acceptable (yes/no)
Professionals Laundering work clothes	1 /NO PPE	0.05	3,00E-05	0,06	Yes

Scenario [16]: Non-Professionals Laundering work clothes

Scenario	Tier	$AEL_{long-term}$ mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/AEL (%)	Acceptable (yes/no)
Non-Professionals Laundering work clothes	1 /NO PPE	0.5	4,55E-05	0,01%	Yes

2.2.6.1.6 Risk for Combined Scenarios

Users	Combined Scenarios	Tier	$AEL_{long-term}$ mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake / AEL (%)	Acceptable (yes/no)
Trained professionals	Brushing + M& L + cleaning brushes + Injection (3)+(8)+(9)+(4) + Handling (5)+ Laundering (15)	(3) Tier 2/Gloves+[(8)+(9)+(4)] Tier 1 + (5) Tier 2/Gloves+ (15) Tier1	0.05	1,18E-01	2,36E+02	No
Trained professionals	Brushing + M& L + cleaning brushes + Injection (3)+(8)+(9)+(4) + Handling (5)	(3) Tier3/Gloves and coverall+[(8)+(9)] Tier1 +(4) Tier2 Gloves + (5) Tier2/Gloves	0.05	5,00E-02	1,00E+02	Yes

Non-professionals	Brushing + M& L + cleaning brushes + handling (6)+(8)+(9)+(7)+ Laundering(16)	Tier 1 no PPEs	0.5	1,29E-01	2,58E+01	Yes

2.2.6.1.7 Risk assessment of effect due to presence of substance(s) of concern SoCs

According to *Guidance on the BPR: Volume III Parts B+C Version 4.0 December 2017; Annex A: Substances of Concern – Proposed Human Health (Toxicology) Assessment Scheme for Authorisation of Biocidal Products*, a risk assessment has been performed for all SoCs in the biocidal product.
One SoCs has been identified in product:

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Petrosol D 15/20	Hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, <2% aromatics	Solvent	64742-48-9	919-857-5 (Provisional)	92.07

Hydrocarbons C9-C11 are present in the biocidal product at concentrations leading or contributing to the classification of the product according to Directive 1999/45/EC or the CLP Regulation:

- Asp. Tox. 1 H304 May be fatal if swallowed and enters airways
- STOT-RE 3 H336 May cause drowsiness or dizziness

This SoC ie assigned to product hazard classification band A:

Band	**Classification of biocidal product according to CLP Regulation due to classified SoC**	**Associated evaluation/risk management requirements**
A	Acute Tox 4 (H332, H312, H302) STOT SE 2 (H371) **Asp Tox 1 (H304)** EUH066 **STOT SE 3 (H336)** Eye Irrit 2 (H319**)** STOT SE 3 (H335) Skin Irrit 2 (H315)	Application of P-statements normally associated with concerned H-statements

It is proposed that for these SoCs, appropriate risk mitigation measures, in the form of the the precautionary (P)-statements normally associated with the concerned hazard (H)-statements under the CLP Regulation, have to be applied:

P261 Avoid breathing dust/fume/gas/mist/vapours/spray
P271 Use only outdoors or in well-ventilated area.

2.2.6.1.8 Risk for consumers via residues in food

The product is not intended to be used in places where food is kept or entrance in contact with food during its application. Therefore, no risk is derived for consumers via residues in

food. In addition, in order to avoid any potential risk by its use, the following RMM is set on product's label:

- *Do not use on wood which may come in direct contact with food feeding stuff and livestock animals.*

As the product is to be used for preventive and curative treatment of interior woods that do not come in direct contact with food and feedstuff, the existing MRLs are not expected to be exceeded.

Risk charactarisation conclusions:

Summary table risk assessment for human health			
Scenario	**Scenario**	**Conclusion**	**Exposed group**
1.	Vacuum-pressure application	A **safe** situation has been for Industrials (Trained professionals) vacuum pressure application when gloves and impermeable coverall (PF 90%) are worn.	Industrial (Trained-Professionals)
2.	Spraying application	An **unsafe** situation has been identified for Professionals and Trained Professionals spraying application.	Trained-Professionals Professionals
3.	Brushing application	A **safe** situation has been identified for Professionals and Trained Professionals brushing when gloves and impermeable coverall (PF 90%) are worn.	Trained-Professionals Professionals
4.	Injection application	A **safe** situation has been identified for Professionals and Trained professionals injection application.	Trained-Professionals Professionals
5.	Handling treated timber	A **safe** situation has been identified for Professionals and Trained professionals handling treated timber when gloves are worn.	Trained-Professionals Professionals
6.	Brushing application	A **safe** situation has been identified for non-professionals brushing.	Non-Professionals
7.	Handling treated timber	A **safe** situation has been identified for non-professionals handling treated timber.	Non-Professionals
8.	Mixing and loading	A **safe** situation has been identified for Trained profesionals, professionals and non-professionals mixing and loading product when gloves and clothes are worn.	Trained-professionals Professionals Non-Professionals
9	Cleaning brush equipment	A **safe** situation has been identified for trained professionals, professionals and non-professionals cleaning brush equipment.	Trained-professionals Professionals Non-Professionals
10.	Cutting and sanding	A **safe** situation has been identified for trained-professionals and professionals cutting and sanding treated wood.	Trained Professionals, Professionals.
11.	Cutting and sanding	A **safe** situation has been identified for trained-professionals and non-professionals for cutting and sanding treated wood.	Non-professionals
12.	Chewing wood off cut	A **safe** situation has been identified for toddler chewing treated wood chips.	General public (toddler-acute)

Summary table risk assessment for human health			
Scenario	**Scenario**	**Conclusion**	**Exposed group**
13.	Playing and mouthing on weathered structure	A **safe** situation has been identified for toddler playing and mouthing on playground weathered wood structure outdoors.	General public (toddler-chronic)
14.	Inhalation residues indoors	A **safe** situation has been identified for general public inhaling volatilised residues indoors.	General public
15.	Laundering contaminated work clothing	A **safe** situation has been identified for trained-professionals and professionals laundering contaminated work clothing at home.	Trained-Professionals, Professionals.
16.	Laundering contaminated work clothing	A **safe** situation has been identified for trained-professionals, professionals and non-professionals laundering contaminated work clothing at home.	Non-professionals.
Combined scenarios 3+8+9+ 15	Brushing + M&L + handling + laundering	A **safe** situation has been identified for Trained-professionals and professionals mixing and loading, brushing, handling wood and cleaning brushes when gloves and impermeable coverall (PF 90%) are worn and laundering clothes without PPEs.	Trained-Professionals, Professionals
Combined scenarios 3+4+8+9 +15	Brushing + Injection + M&L + handling + laundering	A **safe** situation has been identified for non-professionals mixing and loading, brushing and injection application, handling wood and cleqning brushes when gloves and impermeable coverall (PF 90%) are worn and laundering clothes without PPEs.	Trained-Professionals, Professionals
Combined scenarios 6+8+9+ 16	Brushing + M&L + handling + laundering	A **safe** situation has been identified for non-professionals brushing, mixing and loading, handling wood, cleaning brushes and laundering clothes.	Non-Professionals

2.2.7 Risk assessment for animal health

Not applicable. No animal exposure is foreseen.

The product is intended to be used indoors on wood surfaces (beams, posts, window frames,…) without animal presence, hence, no animal exposure is foreseeable.

In adition, to prevent any exposure of animals the following RMMs are included:

- *Keep away from food, drink or animal feedstuffs.*
- *Do not use on wood which may come in direct contact with food, feeding stuff, and livestock animals*
- *Keep children and pets away from treated surfaces until they have dried.*
- *Avoid prolonged contact of pets, particularly cats, to treated surfaces.*

2.2.8 Risk assessment for the environment

Please notice that the environmental risk assessment is reported as provided by the applicant. The ES CA position is presented in grey boxes at the end of each part of the environmental section**.**

2.2.8.1 Effects assessment on the environment

Aquatic compartment

Data of the effect assessment with relevance to the aquatic compartment for the active substance can be found in CAR of the active substance. There are several acute toxicity studies available: *Danio rerio* (fish), *Oncorhyncus mykiss* (fish), *Daphnia magna* and algae.

- PNEC for aquatic organisms

$PNEC_{aquatic}$ was derived from the available short-term studies on aquatic organisms (fish, Daphnia and algae) for the active substance permethrin by applying an assessment factor of 10 to the NOEC from the Daphnia reproduction study.

$PNEC_{aquatic}$ = 4.7x10^{-7} mg/l

- PNEC for STP microorganisms

According to Permethrin's CAR the PNEC for micro-organisms is stablished at the value indicated below:

$PNEC_{microorganisms}$ (STP) = 0.00495 mg/L

- PNEC for sediment-dwelling organisms

According to Permethrin's CAR the PNEC for freshwater sediment is stablished at the value indicated below:

$PNEC_{sediment}$ = 0.001 mg/kg dwt (2.17 x 10^{-4} mg/Kg wwt)

Atmosphere

According to the TGD on Risk Assessment (ECB Part II, 2003), there is currently no appropriate guidance to calculate a PNECair. However, volatilization of Permethrin is considered to be negligible based on the vapour pressure (2.155 x 10^{-6} Pa at 20°C, 25:75 cis:trans) and Henry constant (4.6 x 10^{-3} - > 4.5 x 10^{-2} Pa m^3 mol^{-1}). The software AOPWIN v1.91, which utilises QSAR methods, was used to calculate an atmospheric half-life value of 0.701d for the gas phase reaction of Permethrin with photo-chemically produced hydroxyl radicals (24-hour day and a hydroxyl radical concentration of 5 x 10^5 radicals/cm^3) and 49.27 d for the gas phase reaction of Permethrin with ozone (assuming a 24-hour day and an ozone concentration of 7 x 10^{11} molecules/cm^3). The calculations show that reaction with hydroxyl radicals would be expected to be the major contribution to atmospheric degradation of Permethrin via gas phase reaction with photo-chemically generated species. Based on the short half-life for this transformation pathway, it is concluded that Permethrin is rapidly degraded and would not be transported over large distances in the atmosphere in gaseous phase.

Terrestrial compartment

According to Permethrin's CAR ADDENDUM (March 2017) the PNEC for soil is established at the value indicated below:

$PNEC_{soil}$ ≥ 0.175 mg/kg wwt

Non compartment specific effects relevant to the food chain (secondary poisoning)

The potential impact of substances on top predators is based on the accumulation of hydrophobic chemicals through food chains and should in principle be assessed by comparing the measured or estimated concentration in the tissues and organs of the top predators with the no-effect concentrations for these predators expressed as the internal dose. Data on internal concentrations in wildlife animals are hardly ever available and most no-effect levels are expressed in terms of concentration in the food that the organisms consume (i.e. mg/kg food). Therefore, the actual assessment is based on a comparison of the predicted concentration in the food of the top predator and the predicted no-effect concentration which is based on studies with laboratory animals.

In order to avoid unnecessary vertebrate testing, we consider that the data submitted in support of the approval of the active substance present in the formulation is sufficient to address this endpoint as it can be considered to represent the worst case.

According to Permethrin's CAR, the active substance is not considered persistent (P) or very persistence (vP) neither bioaccumulative or very bioaccumulative (vB). On the other hand, Permethrin is considered to fulfil the criteria of toxicity and it is considered toxic (T) (log K_{ow} = 4.6).

- Calculation of a predicted no-effect concentration ($pnec_{oral}$)

PNEC data for birds and small mammals which are available from active substance's CAR are summarised below:

$PNEC_{oral}$ (birds) = 16.7 mg/kg food

$PNEC_{oral}$ (small mammals) = 120 mg/kg food

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

No studies have been performed with the formulated product and the classification presented in this report relies on the ecotoxicity data available for the active substance permethrin and the coformulants.

Permethrin has two metabolites greater than 10% in soil - 3-(2,2-dichorovinyl)-2,2-dimethylcyclopropane carboxylic acid (DCVA) and 3-phenoxybenzoic acid (PBA). DCVA has a significantly longer DT50 than the parent compound while that of PBA is significantly shorter. Both have a molar mass approximately half that of the parent compound. Both metabolites can be found in soil, water and sediment. However, following active substance's CAR and BPC Opinion (ECHA/BPC/003/2014) it is noted that (a) metabolite risk ratios are significantly lower than those of the parent compound permethrin due to the lower toxicity for aquatic organisms of both metabolites and (b) there are far fewer metabolite failures than there are for the parent compound permethrin. In addition given the highly conservative nature of the exposure assessment carried out for the metabolites any risk identified is significantly lower than that due to permethrin itself. In view of that the current assessment is focused in the parent compound, permethrin.

Further Ecotoxicological studies

No further data is available on the product. Please refer to the data on the active substance

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

No data is available on the product. Please refer to the data on the active substance.

Supervised trials to assess risks to non-target organisms under field conditions

No data is available on the product. Please refer to the data on the active substance.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

No data is available and is not required as the biocidal product is not in the form of bait or granules.

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

Not applicable.

Foreseeable routes of entry into the environment on the basis of the use envisaged

The product is intended to be used indoors as preventive or curative treatment. Both wood or wood-based product treated with this product are always under cover, fully protected from the weather and not exposed to wetting or also where occasional but not persistent wetting may occur. Therefore, according to ISO 21887 and the "*OECD Series on emission scenario documents*" (2013), the product is classified as Use Class 1 and 2 and according to the same references, the potential emissions to the outer environment from treated wood derived from the professional and non-professional use of this UC1+2 product are considered negligible.

However, when the product is applied at industrial scenario and then wood is stored until their shipping, there is a potential risk for emission of product to the environment. Therefore, the potential emission for industrial preventive processes is estimated in the current report and the environmental compartments of concern are summarized in the table below:

Identification of relevant receiving compartments based on the exposure pathway									
Scenarios	**Fresh-water**	**Freshwater sediment**	**Sea-water**	**Seawater sediment**	**STP**	**Air**	**Soil**	**Ground -water**	**Other: Secondary poisoning**
Automated spray application at industrial treatment	2º	2º	n.r	n.r.	1º*	1º	2º	2º	n.r.

Identification of relevant receiving compartments based on the exposure pathway									
Scenarios	**Fresh-water**	**Freshwater sediment**	**Sea-water**	**Seawater sediment**	**STP**	**Air**	**Soil**	**Ground -water**	**Other: Secondary poisoning**
Life cycle stage Use Classes 1 & 2	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.

n.r. = Not relevant
* Worse case situation as residue after application and storage must be disposed as hazardous waste.

ESCA:

Emission to the environment can occur from industrial application and storage. According to the ESD for PT8 it can be assumed that most storage places for treated wood are sealed to prevent any release to the soil. Furthermore, release of wood preservatives from the treatment plants to the STP is not permitted anymore. These exposure scenarios are however listed in the ESD and have been assessed by the applicant.

Further studies on fate and behaviour in the environment (ADS)

No data is available. Please refer to the data on the active substance.

Leaching behaviour (ADS)

No data is available. Please refer to the data on the active substance

Testing for distribution and dissipation in soil (ADS)

No data is available. Please refer to the data on the active substance.

Testing for distribution and dissipation in water and sediment (ADS)

No data is available. Please refer to the data on the active substance.

Testing for distribution and dissipation in air (ADS)

No data is available. Please refer to the data on the active substance.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

No data is required as the biocidal product is not intended to be applied to surface waters.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

No data is required as the biocidal product is not intended to be used outside.

2.2.8.2 Exposure assessment

The product is mainly intended to be used indoors as preventive or curative treatment. Both wood or wood-based product treated with this product are always under cover, fully protected from the weather and not exposed to wetting or also where occasional but not persistent wetting may occur.

According to ISO 21887 and the "*OECD Series on emission scenario documents*" (2013), the product is classified as Use Class 1 and 2 and according to the same references, the potential emissions to the outer environment from treated wood derived from the use of this UC1+2 product in service life are considered negligible and the environmental risk assessment is considered unnecessary for this life cycle stage (service life). However, when the product is applied at industrial scenario and then wood is stored until their shipping, there is a potential risk emission of product to the environment.

The environmental exposure assessment of CORPOL TRATAMIENTO DE MADERA ANTIXILOFAGOS has been developed in accordance with the recommendations of the OECD Emission Scenario Document for wood preservatives (PT8) and the Technical Guidance Document (TGD) on risk assessment (ECB Part II, 2003).

ESCA:

We agree with the explanation given by the applicant. The product is to be used for wood UC1 and UC2. As described in the ESD for PT8, the emission to the environment from wood UC1 and UC2 are considered negligible Emission to the environment can occur from industrial application and storage. According to the ESD for PT8 it can be assumed that most storage places for treated wood are sealed to prevent any release to the soil. Furthermore, release of wood preservatives from the treatment plants to the STP is not permitted anymore. These exposure scenarios are however listed in the ESD and have been assessed by the applicant.

General information

Assessed PT	PT 8 – Wood preservative
Assessed scenarios	[**Scenario 1**] - Product application at industrial treatment by automated spraying and storage before shipping
ESD(s) used	*Emission Scenario Documents for Product Type 8*
Approach	The total emission derived from this scenario can be split in two sub-scenarios: ***Scenario 1a:*** Automated spraying treatment. ***Scenario 1b:*** Storage treated wood after Automated spraying treatment. In both cases, different sizes of treated plant are deemed: • Small plant • Large plant *(Both are regarded as optional sizes for automated spraying treatment (ENV/JM/MONO(2013)21)).*
Distribution in the environment	Calculations based on EUSES 2.2 have been used to estimate the environmental emissions. Outputs of these estimations can be found in section 13 of IUCLID dossier and in Annex 3.2 of

	the current dossier.
Groundwater simulation	FOCUS PEARL model was performed.
Confidential Annexes	Yes
Life cycle steps assessed	- *Scenario 1* Production: No Formulation No Use: Yes Service life: No
Remarks	*All emission scenarios have been developed by following the ESD – PT8*

The following table shows some of the input parameters considered in the environmental assessment for each active substance:

Input parameters (only set values) for calculating the fate and distribution in the environment		
Input	**Value**	**Unit**
Molecular mass	391.29	g/mol
Melting point	33 – 35	ºC
Boiling point	305	ºC
Vapour pressure	$2.155x10^{-6}$	Pa at 20ºC
Water solubility	<0.00495	mg/l
Log Octanol/water partition coefficient (Kow)	$4.5x10^{-2}$	Log 10
Henry's Law Constant	$9.2x10^{-5}$	$Pa/m^3/mol$ (25ºC)
Biodegradability	No readily biodegradable	
Degradation in soil	DT_{50} = 106	days
Degradation in water compartment	DT_{50} >200	days
Rate constant for degradation in air	Although there is a photo-oxidative degradation in air (DT_{50}= 0.47 days (based on a 12-hour day and hydroxyl radical concentration of 1.5 x 10^6 radicals/cm^3) or 0.701 days (based on a 24-hour day and hydroxyl radical concentration of 5 x 10^5 radicals/cm^3). Fate and behaviour in air is not regarded relevant because there is no relevant release of the compound to the air compartment.	days
K_{oc}	26,930	-
Other degradation and transformation rates		

n.a. = not available

Emission estimation

In accordance with the approach taken in the AR, the Predicted Environmental Concentration (PEC) in surface water, groundwater and sediment were calculated for the intended uses. The following PEC values were calculated by the published recently ESD's

excel sheets (15/11/2017) and the Technical Guidance Document on Risk Assessment part II (TGD II).

The PEC in groundwater is calculated as a direct function of the PEC in soil, and therefore full calculations for both soil and groundwater are presented in the current dossier.

Scenario [1] – Automated spraying

This type of superficial application process is typically used in sawmills and carpentry / joinery industries. Concentrates of the wood preservative are diluted with water, to prepare a ready for use treatment solution. The wood, whether in debarked logs or fully or partly machined timber are moved through one or more longitudinal or transversal boxes on a continuously moving conveyor system.

The product is applied as a spray which is usually as a coarse spray using a particle spray size to ensure the wetting of the timber with the correct amount of wood preservative.

The spray boxes are relatively contained and splashguards surround the spraying boxes to eliminate any droplets of spray from entering the rest of the mill area and may have local exhaust ventilation.

After the timber has been treated it is stacked or sorted, mechanically either dries on the conveyor belt or in the post treatment drip dry conditioning area before being moved off-site to manufacturers or used on site.

The treatment apparatus is typically established in a contained or bounded area manufactured from materials resistant to the wood preservative product. Provision is made for the collection, recycling and reuse of wood preservative collected from the conveyor or drip dry area. The release of product's residues from the treating installation or where the treated timber is stored into a surface water drain or drain connected to a Sewage Treatment Plant (STP) is not permitted and so any installation where this occurs is in contravention of environmental protection legislation and the licence to operate the treatment process.

Following the ESD excel-sheets for automated spraying application, two sub-scenarios have been developed in function of the size of sawmill which has effect in the area of wood treated per day.

The following table shows the used parameters in the environmental emission assessment for the automated dipping scenario.

Input parameters for calculating the local emission from automated spraying process			
Input	**Value**	**Unit**	**Remarks**
Scenario: **1.a – Automated spraying (application)**			
Area of wood treated per day in a			
- Large plant	20000	m^2/d	(considered as worse case)
- Small plant	2000	m^2/d	
Application rate of the product	0.1	L/m^2	
Concentration of substance in diluted product	0.0035	[-]	
Quantity of a substance applied per m^2 of wood	8.03E-04	Kg/m^2	
Fraction released to facility drain	0.03	[-]	(water solubility > 100 mg/l)
Fraction released to air	0.001	[-]	(vapour pressure at 20ºC <

Input parameters for calculating the local emission from automated spraying process			
Input	**Value**	**Unit**	**Remarks**
Scenario: **1.a – Automated spraying (application)**			
			0.005Pa)
Fraction of spray drift deposition	0.001	[-]	

As in the scenario before, the environmental risk derived from the storage of treatment wood during the application and before shipping has been taken in account as a worse case for the automated spraying application:

Input parameters for calculating the local emission from automated spraying process			
Input	**Value**	**Unit**	**Remarks**
Scenario: **1.b – Automated spraying (storage)**			
Effective surface area of treated wood, considered to be exposed to rain, per 1 m^2 storage area (i.e. soil)	11	$m^2.m^{-2}$	
Surface area of the storage place in a large plant	790	m^2	
Duration of the initial assessment period	30	D	
Duration of a longer assessment period	7300	D	Value agreed at the WG IV 2015 (Tolyfluanid discussion) (20 years)
Average daily flux i.e. the average quantity of a substance that is daily leached out of 1 m^2 of treated wood during 3 day storage period	0.4E-04	$kg.m^{-2}.d^{-1}$	Tier 1: worse-case assumption where 50% of the active substance is assumed to leach after an initial time period of 30 days and 100% of the active substance is assumed to leach after a given longer time period = (Qa.i.*50% /30days)
Volume of treated wood stacked per m^2 of storage area (i.e. soil)	2	$m^3.m^{-2}$	
Bulk density of wet soil	1700	Kg/m^3	
Soil depth	0.5	M	
Fraction of rainwater running off the storage site	0.5	[-]	
Flow rate of surface water (creek/river)	25920	$m^3.d^{-1}$	This value corresponds to 0.3 $m^3.s^{-1}$ which is the default value for a small creek.

Fate and distribution in exposed environmental compartments

The table below shows the relevant receiving compartments based on the exposure pathway derived from industrial preventive treatment and assessed in the current report:

Identification of relevant receiving compartments based on the exposure pathway

Scenarios	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other: Secondary poisoning
Automated spray application at industrial treatment	2º	2º	n.r	n.r.	1º	1º	2º	2º	n.r.

Calculated PEC values

Please see in the table below the PECs obtained for each environmental compartment at scenario of automated spraying application:

PEC values derived from spraying application and storage before shipping for large plant			
Compartments	**Units**	**Active substance**	
		Large plant	**Small plant**
Scenario [1.a] - During application stage			
Annual average local PEC in air	[mg.m^{-3}]	7.34E-06	7.34E-07
PEC for micro-organisms in the STP	[mg.l^{-1}]	8.02E-04	8.02E-05
Local PEC in surface water during initial emission episode	[mg.l^{-1}]	8.02E-05	8.02E-06
Local PEC in fresh-water sediment during emission episode	[mg.kgwwt^{-1}]	8.2E-05	8.2E-06
Local PEC in agric. soil (total) averaged over 30 days	[mg.kgwwt^{-1}]	1.74E-04	1.74E-05
Local PEC in agric. soil (total) averaged over 180 days	[mg.kgwwt^{-1}]	1.73E-04	1.73E-05
Local PEC in grassland (total) averaged over 180 days	[mg.kgwwt^{-1}]	1.70E-04	1.70E-05
Local PEC in pore water of grassland	[mg.l^{-1}]	5.44E-04	5.44E-05
Local PEC in groundwater under agricultural soil	[mg.l^{-1}]	5.52E-04	5.52E-05
Local PECoral,fish Concentration in fish for secondary poisoning (freshwater)	[mg.kg$_{food}$]	4.66E-05	4.66E-06
Predicted Environmental Concentration in food for terrestrial secondary poisoning	[mg.kg$_{food}$]	2.20E-04	2.20E-05
Scenario [1.b] - During storage stage			
Local PEC in surface water during:			
Time 1 – initial emission episode	[mg.l^{-1}]	6.73E-03	6.73E-03
Time 2 – over a longer duration		6.73E-03	6.73E-03
Local PEC in fresh-water sediment during:			
Time 1 – initial emission episode	[mg.kgwwt^{-1}]	6.88E-03	6.88E-03
Time 2 – over a longer duration		6.88E-03	6.88E-03
Local PEC in agric. soil (total) averaged over each time			
Time 1 – initial emission episode	[mg.kgwwt^{-1}]	7.794	7.794
Time 2 – over a longer duration		1.9E+03	1.9E+03
Local PEC in pore water of agricultural soil			
Time 1 – initial emission episode	[µg.l^{-1}]	2.49E+04	2.49E+04
Time 2 – over a longer duration		6.07E+06	6.07E+06

Further data related to emission calculations can be found in Annex Section 3.2.

ESCA:

This evaluation has not been reviewed by the ESCA since no emission to the enviorment

are expected.

2.2.8.3 Risk characterisation

Not relevant environmental risk is foreseen when the product is applied indoors as preventive or curative treatment by professional and non-professional users because in these cases wood or wood-based product treated with this product are always under cover, fully protected from the weather and not exposed to wetting or also where occasional but not persistent wetting may occur. Therefore, according to ISO 21887 and the "*OECD Series on emission scenario documents*" (2013), the product is classified as Use Class 1 and 2 and according to the same references, the potential emissions to the outer environment from treated wood derived from the use of this UC1+2 product by professional and non-professional users are considered negligible and the environmental risk assessment is considered unnecessary for these cases.

However, when the product is used at industrial treatment, potential risk may occur during the application and storage phases until the shipping of the treated wood to the market place. Therefore, the environmental risk characterisation is focused in this last treatment.

The risk characterization ratio (RCR) is calculated as a quotient between the Predicted Environmental Concentrations (PECs) and the Predicted Non-Effect-Concentrations (PNECs) for the different compartments such as air, surface water, sediment, Sewage Treatment Plants (STP), soil (agricultural and grassland) and groundwater. If RCR for any environmental compartment is >1, there is a potential risk for this compartment.

According with the active substances' CARs, the following predicted no effect concentration values (PNECs) have been estimated for each compartment and for the active substance:

PNECs	***Units***	**Permethrin**	**DCVA**	**PBA**
PNECstp	[mg.l^{-1}]	0.00495	-	-
PNECwater	[mg.l^{-1}]	4.70E-07	0.015	0.01
PNECsed	[mg.kgwwt^{-1}]	2.17E-04	0.012	0.009
PNECsoil	[mg.kgwwt^{-1}]	8.76E-02	4.6	1.44
PNECgw	[mg.l^{-1}]	1.00E-04	-	-
PNECoral birds	[mg.kg$_{food}^{-1}$]	16.7	-	-
PNECoral mammals	[mg.kg$_{food}^{-1}$]	120	-	-

Taken into account the above values, the risk due to the active substance at industrial scenario was calculated for the main environmental compartments.

Atmosphere

Conclusion: With regard to exposure scenario, no environmental risk exposure is foreseen for the atmosphere. The application of the product is done in closed and sealed tanks where the evaporation is not considered of concern. In addition, the physical-chemical properties of each active substance in the environment, such as vapour pressure (<0.1 mPa) and molecular weight (391.21 g/mol), indicate that the active substance nor its metabolites will readily volatilise into the atmosphere at ambient temperature and pressure.

In addition, there is not $PNEC_{air}$ available for some of the active substances to be compared to the PEC_{air} of the product. However, considering the low volatility of the active substances, and following the assessment report of Regulation (EU) n°528/2012 concerning the making available on the market and use of biocidal products (July, 2013); emissions to the air compartment are expected to be low with no risk associated to the air compartment.

Sewage treatment plant (STP)

The following table shows the derived risk from the corresponding PEC for scenario:

Summary table on calculated PEC/PNEC values from STP					
Scenario		**PEC_{STP} (mg/L)**	**$PNEC_{STP}$ (mg/L)**	**PEC_{STP}/ $PNEC_{STP}$**	**RISK**
Stage 1: Automated-spray application (industrial)	Large plant	8.02E-04	4.95E-03	0.16	No
	Small plant	8.02E-05		0.016	No

Conclusion:

No risk is foreseen for STP compartment by the use of CORPOL TRATAMIENTO DE MADERA ANTIXILOFAGOS at industrial application by automated spraying.

Aquatic compartment

Surface water

Summary table on calculated PEC/PNEC values from surface water					
Scenarios		**PEC_{sw} (mg/L)**	**$PNEC_{sw}$ (mg/L)**	**PEC_{sw}/ $PNEC_{sw}$**	**RISK**
Stage 1: Automated-spray application (industrial)	Large plant	8.02E-05	4.70E-07	**170.66**	**Yes**
	Small plant	8.02E-06		**17.07**	**Yes**

Values on bold are above the trigger value

Sediment

Summary table on calculated PEC/PNEC values from sediment					
Scenarios		**PEC_{sed} (mg/kgwwt)**	**$PNEC_{sed}$ (mg/Kg wwt)**	**PEC_{sed}/ $PNEC_{sed}$**	**RISK**
Stage 1: Automated-spray application (industrial)	Large plant	8.20E-05	2.17E-04	0.38	No
	Small plant	8.20E-06		0.04	No

Conclusion:

No risk is foreseen for sediment compartment by the use of CORPOL TRATAMIENTO DE MADERA ANTIXILOFAGOS at industrial application by automated spraying. However, unacceptable risk is disclosed for surface water so aquatic compartment is deemed at risk.

Soil

Summary table on calculated PEC/PNEC values from soil					
Scenarios		**PEC_{soil} (mg/kgwwt)**	**$PNEC_{soil}$ (mg/Kg wwt)**	**PEC_{soil}/ $PNEC_{soil}$**	**RISK**
Stage 1: Automated-spray application (industrial)	Large plant	1.74E-04	0.175	9.94E-04	No
	Small plant	1.74E-05		9.94E-04	No

Conclusion:

No risk is foreseen for soil compartment by the use of CORPOL TRATAMIENTO DE MADERA ANTIXILOFAGOS at industrial application by automated spraying.

Groundwater

Summary table on calculated PEC/PNEC values from groundwater					
Scenarios		**PEC_{gw} (mg/l)**	**Trigger value (mg/l)**	**PEC_{gw}/ Trigger value**	**RISK**
Stage 1: Automated-spray application (industrial)	Large plant	5.52E-04	1E-04	**5.52**	**Yes**
	Small plant	5.52E-05		0.55	No

Conclusion:

No risk is foreseen for groundwater compartment by the use of CORPOL TRATAMIENTO DE MADERA ANTIXILOFAGOS at industrial application by automated spraying on small plants. However, when it is applied on large plants an unacceptable risk is foreseen for groundwater compartment.

Primary and secondary poisoning **(non-compartment specific effects relevant to the food chain)**

- For freshwater

Summary table on calculated PEC/PNEC values from secondary poisoning at freshwater					
Scenarios		**$PEC_{oral,fish}$ (mg/ kgwwt)**	**$PNEC_{oral,fish}$ (mg/ kgwwt)**	**$PEC_{oral,fish}$/ $PNEC_{oral,fish}$**	**RISK**
Stage 1: Automated-spray application (industrial)	Large plant	4.66E-05	16.7	2.79E-06	No
	Small plant	4.66E-06		2.79E-07	No

- For terrestrial

Summary table on calculated PEC/PNEC values from secondary poisoning at soil					
Scenarios		**$PEC_{oral,worm}$ (mg/ kgwwt)**	**$PNEC_{oral,worm}$ (mg/ kgwwt)**	**$PEC_{oral,worm}$/ $PNEC_{oral,worm}$**	**RISK**
Stage 1: Automated-spray application (industrial)	Large plant	2.20E-04	120	1.32E-05	No
	Small plant	2.20E-05		1.32E-06	No

Conclusion:

No risk exposure is foreseen for secondary poisoning both aquatic or terrestrial compartment.

Mixture toxicity

Not relevant due to the intended use of this product.

Aggregated exposure (combined for relevant emmission sources)

Not applicable as the product is only intended to be used as PT8 and no concern is derived from the correct uses (UC-1 and UC-2) of this product.

Overall conclusion on the risk assessment for the environment of the product
No concern is derived from the correct use of this product by professional and non-professional users for the environment. However, when the product is applied at industrial preventive use, unacceptable risk is expected for surface water and groundwater for large plants and surface water also for small plants. Thus and taken into account that these risks are due to emissions from industrial facilities, the containment of the emission to the faculty drain and subsequent storage under cover on an impermeable surface, are proposed as an appropriate risk mitigation measures that will reduce the environmental risk to zero.

ESCA: Overal conclusion:

We agree with the evaluation presented by the applicant.

In order to evoid any emission to the environment from the industrial application, the following risk mitiation measures are needed:

Industrial application processes must be carried out within a contained area, situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump).

Freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water and that any losses of the product shall be collected for reuse or disposal.

To avoid any amission to the environment during the application of the biocidal product in uses 2 and 3, the following contion of use is needed

During product application (to timbers) and whilst surfaces are drying, do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin) and disposed of in a safe way (for professional users) and / or Before treatment, cover floor around and under object to treat with a disposable,non-permeable protection sheet (e.g. plastic) to avoid spilling of product on the floor (for non professional users).

2.2.9 Measures to protect man, animals and the environment

Please, regarding this section, see the risk mitigation measures included in the description of each use authorised in the SPC/PAR.

Recommended methods and precautions concerning storage of biocidal product; shelf life of product:

- Keep out of sun exposure and frost.
- Store in the original container.
- Store in a dry place and in closed containers.

Recommended methods and precautions concerning handling and transport

Handling:

- Before using the product read the label carefully.
- To avoid risks to man and the environment, comply with the instructions for use.
- Contains Permethrin. May produce an allergic reaction.
- Do not use in presence of people and / or domestic animals.
- Do not use or apply near food, utensils, drink and animal feedingstuffs.
- Do not use in areas where animals can be present or treated wood can be reached by animals.
- Provide adequate ventilation to the premises where the product is applied.
- Do not mix with other chemicals.
- Instructions for use by industrial qualified personnel: confirm that all the drained product is collected and contained during the application and storage of the wood during the industrial treatment. And bear out the treated wood is stored under cover on an impermeable surfaces
- Instructions for use by qualified personnel: autoclave, extended immersion or injection.
- Instructions for use by the general public: brushing.
- The safety period recommended for environmental use is 12 hours. This period will not be lower than the time to fix the product.

Indications for the transport:

- ONU number: UN1306
- Official Classification of Transport: Wood preservatives, liquid
- Class of dangerous goods: 3
- Group of packaging: III
- Dangerous for the environment: Yes

Recommended methods and precautions concerning fire:

Extinguishing Media:

• Suitable extinguishing media: extinguish the fire using foam, powder, CO2 or water spray

• Unsuitable extinguishing media: Do not use jets of water to extinguish the fire, only to cool areas and packages near the heat source.

Special hazards arising from the substance or mixture: Do not breathe vapours. Combustion gases of organic materials must always be regarded as toxic by inhalation.

Advice for firefighters: Use masks with filters for organic products in confined areas.

Particulars of likely direct or indirect adverse effects:

Conditions to avoid:

Avoid contact with strong acids and alkalis and organic matter.

Hazardous decomposition products:
No decomposition products are generated if stored and handled correctly. Carbon monoxide, carbon dioxide, nitrogen oxides, iodine vapours and other toxic gases can be formed in case of fire or thermal decomposition, therefore, in case of fire or combustion, avoid inhalation of the fumes.

First aid instructions, antidotes:
Poisoning may cause:
Eye and skin irritation. Alteration of nervous system. Chemical pneumonia by aspiration.

First aid:
Remove the person from contaminated area.
Remove contaminated clothing.
In the case of contact with eyes, rinse with plenty of water for at least 15 minutes. Remember to remove the contact lenses.
Wash skin with soap and water, without rubbing.
Never give anything by mouth. Do not induce vomiting.
Check breathing, if necessary, provide artificial respiration.
Take the patient to hospital and take the container or label.
DO NOT LEAVE THE INTOXICATED PERSON ALONE AT ANY TIME.

Therapeutic advice for physicians and health staff: Symptomatic treatment.

Emergency measures to protect environment in case of accident:

Personal precautions, protective equipment and emergency procedures:

No action involving any risk personal without suitable training must be done. Keep unnecessary and unprotected personnel from entering (see Section 8).

Environmental precautions:

Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform to the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up:

Channelling large quantities and collect in containers; dispose them according to local regulations. Wash the small amounts with water. Remove the used water according to local regulations.

Instructions for safe disposal of the biocidal product and its packaging:
Product:

The residues of product should be managed according to current regulations through authorized waste managers. Waste must not be disposed through sewage systems.

Containers:

Use for qualified professional staff: Empty containers should be managed according to current regulations through authorized waste managers.

Use by the general public: Empty containers must be placed in clean points or points established by the local authority in accordance with their respective legislations.

2.2.10 Assessment of a combination of biocidal products

For biocidal products that are intended to be authorised for the use with other biocidal products.

2.2.11 Comparative assessment

Not applicable.

3 ANNEXES

3.1 List of studies for the biocidal product

Section No.	Author(s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
2.2.2; 2.2.4	[redacted]	2016	Title: Physico-chemical properties, validation of the analytical method and chemical analyses of the biocidal product PERMETHRIN 0.35% before and after an accelerated storage procedure for 14 days at 54± 2°C, in compliance with CIPAC MT 46.3 method (Handbook J, 2000 Report No 402/15/1187F-e. FCBA	Yes	QUÍMICA DE MUNGUÍA, S.A.
2.2.2	[redacted]	2018	Determination of the expiry date: testing at 24 months (CORPOL TRATAMIENTO DE MADERA ANTIXILÓFAGOS) Report No COA-402/15/1187F/1/k/ T24M-e FCBA	Yes	QUÍMICA DE MUNGUÍA, S.A.
2.2.3	[redacted]	2016	Exxol D40 (CAS 64742-47-8) Permethrin (0.35%): Determination of Auto-Ignition Temperature (Liquids and Gases) Report No DS76HT ENVIGO	Yes	QUÍMICA DE MUNGUÍA, S.A.
2.2.3	[redacted]	2021	Determination of the corrosive properties of the test item "Gorpol Tratamiento de madera antixilofagos.	Yes	QUÍMICA DE MUNGUÍA, S.A
2.2.5	[redacted]	2016	Title: Preventive action against larvae of *Hylotrupes bajulus* according to EN 46-1 with EN 73. Test facility: FCBA Institut Technologique, France Report No. 401/15/230F/a.	Yes	QUÍMICA DE MUNGUÍA, S.A.
2.2.5	[redacted]	2005	Title: Determination of efficacy threshold against larvae of *Hylotrupes bajulus* (Linnaeus) according to EN 47:1988 Test facility: CIDEMCO, Biotek-Maderas, Spain Report No. 10583	Yes	QUÍMICA DE MUNGUÍA, S.A.
2.2.5	[redacted]	2004	Title: Determination of efficacy threshold against *Reticulitermes santonensis* Feytaud according to EN 117:1989 Test facility: CIDEMCO, Biotek-Maderas, Spain Report No. 9855.3	Yes	QUÍMICA DE MUNGUÍA, S.A.
2.2.5	[redacted]	2017	Title: Determination of preventive action against *Reticulitermes* species according to EN 118:2013. Test facility: TECNALIA, Spain	Yes	QUÍMICA DE MUNGUÍA, S.A.

			Report No. 062358-1-a		
2.2.5	[redacted]	2016	Title: Curative action against *Hylotrupes bajulus* according to NF EN 1390 Test facility: FCBA Institut Technologique, France Report No. 401/15/230F/c	Yes	QUÍMICA DE MUNGUÍA, S.A.
2.2.5	[redacted]	2017	Title: Curative action against *Lyctus brunneus* according to Pr NF X41-665 Test facility: FCBA Institut Technologique, France Report No. 401/15/230F/e-e	Yes	QUÍMICA DE MUNGUÍA, S.A.
2.2.5	[redacted]	2018	Title: Curative action against *Anobium punctatum* according to NF EN 48 Test facility: FCBA Institut Technologique, France Report No. 401/15/230F/d-e	Yes	QUÍMICA DE MUNGUÍA, S.A.
2.2.5	[redacted]	2005	Title: Determination of curative efficacy against larvae of *Hylotrupes bajulus* (Linnaeus) according to UNE 56408:1982 (equivalent to EN 22:1974) Test facility: CIDEMCO, Biotek-Maderas, Spain Report No. 10583	Yes	QUÍMICA DE MUNGUÍA, S.A.

3.2 Output tables from exposure assessment tools

Corpol TM Human Exposure calculatior

3.3 New information on the active substance

3.4 Residue behaviour

3.5 Summaries of the efficacy studies (B.5.10.1-xx)

Please see table on Efficacy data on section 2.2.1.5.

3.6 Confidential annex

Please see confidential annex.

3.7 Other